EXHIBIT B33

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	)	MDL 16-2738 (FLW)(LHG)
THIS DOCUMENT PERTAINS TO ALL CASES	)	

WEDNESDAY, DECEMBER 19, 2018

CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

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Videotaped deposition of Laura Plunkett, Ph.D., DABT, held at the Four Seasons Hotel, 999 North 2nd Street, St. Louis, Missouri, commencing at 9:12 a.m., on the above date, before Carrie A. Campbell, Registered Diplomate Reporter, Certified Realtime Reporter, Illinois, California & Texas Certified Shorthand Reporter, Missouri & Kansas Certified Court Reporter.

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EXHIBITS

(Exhibits attached to the deposition.)

VIDEOGRAPHER: We are now on the record.

My name is Jacob Arndt. I'm a videographer for Golkow Litigation Services.

Today's date is December 19, 2018, and the time is 9:12 a.m.

This deposition is being held in St. Louis, Missouri, In Re: Johnson & Johnson Products Marketing Sales Practices, for the United States District Court for the District of New Jersey.

The deponent is Dr. Laura Plunkett.

Will counsel please identify themselves?

MR. MEADOWS: Ted Meadows for plaintiffs.

MS. PARFITT: Michelle Parfitt for the plaintiffs.

MR. BEATTIE: Ryan Beattie for plaintiffs.

MR. TISI: Chris Tisi for plaintiffs.

MR. GOLOMB: Richard Golomb for plaintiffs.

MR. LOCKE: Tom Locke for the Personal Care Products Council.

MS. TINSLEY: Caroline Tinsley for PTI Union, LLC, and PTI Royston, LLC.

MR. SULLIVAN: Ryan Sullivan for Imerys.

MS. BOCKUS: Jane Bockus for Imerys.

MR. SMITH: William Smith for Johnson & Johnson.

MS. BRANSCOME: Kimberly Branscome for Johnson & Johnson.

VIDEOGRAPHER: Thank you.

The court reporter is Carrie Campbell and will now swear in the witness.

LAURA PLUNKETT, Ph.D., DABT, of lawful age, having been first duly sworn to tell the truth, the whole truth and nothing but the truth, deposes and says on behalf of the Defendant Johnson & Johnson, as follows:

DIRECT EXAMINATION

QUESTIONS BY MS. BRANSCOME:

Q. All right. Good morning, Dr. Plunkett. I introduced myself right before we started, but my name is Kimberly Branscome, and I am here on behalf of Johnson & Johnson.

Is it your understanding today that you are giving your deposition for the purpose of a Daubert analysis in the MDL related to Johnson's baby powder?

A. That's my understanding, yes.

(Plunkett Exhibit 1 marked for identification.)

QUESTIONS BY MS. BRANSCOME:

Q. I want to start by handing you what I will mark as Plunkett Deposition Exhibit 1.

Do you recognize the document that I just handed you?

A. Yes.

Q. Okay. Have you seen this document before?

A. Yes.

Q. All right. When was this

document provided to you?

A. Either earlier this -- this week or late last week. I don't recall if it was Friday or Monday.

Q. Okay. For the purposes of the record, could you just identify what the document is that I just handed you as Plunkett Deposition Exhibit Number 1?

A. It's a notice of oral and videotaped deposition for myself, dated -- I don't see the date, but probably on the very last -- do you need that or just -- is that enough of an identification?

Q. That's all right.

Now, contained within the deposition notice there is a reference to a request for materials that are identified in more detail in Schedule A.

Do you see that?

A. Yes.

Q. Have you reviewed Schedule A?

A. Yes.

Q. Did you bring any documents with you in response to the request in Schedule A?

A. The only thing that I believe that I had to bring that had not already been provided was additional billing since the time of my last deposition.

Q. Okay. And is it my understanding that the documentation related to additional billing that you have done since your prior deposition was produced yesterday at the deposition in the Forrest case?

A. That's correct.

Q. All right. And the information contained in the documents produced at the Forrest deposition yesterday, do those contain an up-to-date record of the billing that you have submitted for your work in connection with the litigation against Johnson & Johnson?

A. Yes, with the understanding that I haven't submitted a bill for December yet.

Q. Okay. How much time have you spent working in connection with your opinions in the case against Johnson & Johnson related to its baby powder in the

month of December?

A. So I'm -- on all the cases that I am involved in that are pending, not just this deposition?

Q. I'll ask first all cases and then we'll narrow it to the deposition.

A. So in all --

Q. I mean to the MDL, I'm sorry.

A. Okay. So in all cases this month, probably eight hours so far, maybe ten.

Q. Does that include the time that you've spent attending deposition?

A. No, that's not including yesterday's deposition time. I apologize. I forgot about that.

Q. And how much of the eight to ten hours that you have spent this month working on these cases against Johnson & Johnson, setting aside the time you spent in deposition yesterday, relate to the MDL specifically?

A. So it will probably be billed -- it will be one bill for the preparation time because the prep overlapped,

but I'll bill separately for the time I spent yesterday right before the deposition and then at the deposition, so...

Q. What did you do to prepare for your deposition today?

A. I reviewed my reports, the three reports that I filed in the litigation. I had a meeting with attorneys on Monday, and then we had a short meeting yesterday evening because some attorneys arrived that were not here on Monday.

And essentially went through some of the documents that -- went through some of the documents that I had cited in the report in certain paragraphs, just to refresh my memory of what they were. So if you want me to tell you which paragraphs, I can do that.

Q. I will in just a moment. Okay.

A. Want me to repeat that? I'm sorry.

Q. That's all right.

Dr. Plunkett, you referenced the fact that you reviewed specific paragraphs of your expert reports in

preparation for today's deposition.

Could you identify those paragraphs for me?

And it's helpful to you, we can go ahead and mark your three expert reports, if you're referring to all three.

A. I'm going to refer just to the MDL report because that's what we're here to talk about. I mean, if you want to talk about what I did to get ready for yesterday separately or --

MR. MEADOWS: Might be helpful to go ahead and mark them.

MS. BRANSCOME: Why don't we go ahead and just mark the three reports, and then we can walk through.

(Plunkett Exhibits 2, 3 and 4 marked for identification.)

QUESTIONS BY MS. BRANSCOME:

Q. So, Dr. Plunkett, do you have a copy of your three reports in front of you?

A. Yes, I do.

Q. Do those contain any markings, highlightings or flags?

A. No, they don't.

Q. Okay. Do you mind if we mark your copies as the official records?
A. No, that's fine.
Q. So we will mark -- well, let's do this in chronological order. So I am marking as Plunkett Deposition Exhibit Number 2 the expert report of Dr. Plunkett dated October 5, 2016.
Could you confirm, Dr. Plunkett, that that's what I marked as Deposition Exhibit Number 2?
A. Yes, it is.
Q. And then we will mark as Deposition Exhibit Number 3 supplemental expert report of Dr. Laura Plunkett dated August 29, 2018.
Dr. Plunkett, could you confirm that I marked that as Exhibit Number 3?
A. Yes, that's correct.
Q. And then Exhibit Number 4, we will mark the expert report dated November 16, 2018, by Dr. Plunkett that was produced in the MDL.
Could you confirm that I marked that as Deposition Exhibit Number 4?

A. Yes, that's correct.
Q. All right. And so now back to the question of you referenced the fact that you looked at specific paragraphs of your expert report in preparation for today's deposition. If you could, using Deposition Exhibit Number 4, identify which paragraphs you looked at specifically in preparation for the deposition.
A. So it wasn't the paragraphs. There were certain documents in paragraphs, so that's what I was referring to, so...
So starting in paragraph 38 where I'm talking about sort of the timeline of information about human health hazards and talc dust. So I just went back and refreshed on a few of the older papers.
I looked again at the patent documents that are cited in the first bullet.
I looked again at a paper by Eberl, 1948, which is in the last bullet. The patent documents are also there as well.
And that -- so that would be all I pulled in that paragraph.
I believe that those documents

are also cited in paragraph 39 as well, some of those same ones that are...
And then in Section 5 of my report where I'm talking about exposure, I looked again at Parmley and Woodruff. I looked again at Vetner and Iturrulde and Egli and Newton last night.
And the only other thing I looked at is not cited in this report because it came out after the report was filed, and that was -- and I did bring a copy of that. That was the risk assessment that was done in Canada. Some people refer to it as -- by the first author's last name, Taher, T-a-h-e-r. And I may be pronouncing that wrong, but...
(Plunkett Exhibit 5 marked for identification.)
QUESTIONS BY MS. BRANSCOME:
Q. All right. And I see that you brought a copy of that document with you. Just for the purposes of the record, let's mark that as Plunkett Deposition Exhibit Number 5.
Are there any markings, highlightings or notations on that document?

A. No, there's not.
And then the other document I looked at that was not cited in the report, there is a printout from the government of Canada website that talks about some statements on talc, and so I printed that out as well. This was published at the same time that the risk assessment was published.
(Plunkett Exhibit 6 marked for identification.)
QUESTIONS BY MS. BRANSCOME:
Q. All right. We'll mark that for purposes of the record as Plunkett Deposition Exhibit Number 6. We might come back to those documents.
So returning briefly to the deposition notice and the requests in Schedule A, the billing information you produced yesterday and then we just discussed additional information with respect to that, are there any other documents that you have in your possession that are responsive to requests identified in Schedule A that have not been produced?
A. I don't believe so, no.

Everything -- I do believe that there were some objections filed to this, so there's some things that I did not provide based on that.

Some of the things I don't have, too. I think you asked for -- maybe you didn't ask for that. Usually people ask for copies of old depositions, and I don't keep those. And maybe you didn't ask for that, but that's usually a request.

Let me see.

Q. Okay. Now, you mentioned that you met with attorneys on Monday. And who was present at that meeting?

A. So on Monday it was Mr. Meadows, sitting here. Ms. Tucker, Mr. Beattie, were at the meeting on Monday.

Q. All right. And how long did that meeting last?

A. Probably six hours, I guess, six hours with them, and then I also did some other work on my own, but...

Q. Okay. And then you mentioned that you had another meeting last night.

Who was present at that

meeting?

A. So that was probably about an hour, and that would have been Mr. Tisi -- or maybe two hours. Mr. Tisi joined us yesterday afternoon. And Mr. Golomb, too, I'm sorry.

Q. All right. Okay. Now, looking at the three reports that you have produced in the litigation involving Johnson's baby powder, I wanted to get an understanding of how those three reports relate to one another.

So you have the first report that you produced that was dated October 5, 2016. I believe that was originally produced in the Uhl case; is that correct?

A. I'm not sure the name of the first case, but it was in the -- some of the St. Louis cases, yes.

Q. All right. And when did you begin work on that report?

A. You'd have to look at my billing record, which I know was an exhibit to yesterday's deposition. I believe they started in 2015.

Q. All right. And then you produced a supplemental report earlier this year, on August 29, 2018, and that's been marked as Deposition Exhibit Number 3, correct?

A. Yes.

Q. When did you begin work on the supplemental report that you produced at the end of August in 2018?

A. I want to say -- let's see. I want to say sometime in the summer. Maybe as early as May, but I believe May -- May, June time frame of 2018.

My billing would reflect that, so, again, we can pull my billing. And I would have called it preparation of the supplemental report in my billing.

Q. Okay. Why did you choose to draft a supplemental expert report?

A. So over the time I had worked on different trials here in St. Louis particularly, additional documents that were not cited in my original report became reliance materials based on their presentation at trial. So there were enough

of those that I thought it was important to add to the original report with additional documents that I had reviewed over time.

Since October of 2016 through, let's say, the summer of 2018, there were a variety of additional documents that I had -- I had seen.

It was also my understanding that during that time period Johnson & Johnson had provided additional documents that weren't provided or available to me in 2016, so additional discovery that was now available to look at. So some of this is a matter of additional evidence that wasn't available when I wrote my initial -- my initial report.

Q. All right. Now when you say the additional documents became reliance materials in trial, what do you mean by that?

A. So additional documents that we refer to in trial that I use to support opinions that weren't necessarily specifically cited within the body of my report or described within the body of my report. They were likely on my larger

reliance list, but they weren't things that were cited.

In other words, if you look at my original report in -- when I say the body, the paragraphs. I always put a reference list and then I'll have Bates numbers. So during trial, things that were from my larger reliance list that weren't specifically discussed in my report became support for different opinions that -- based on questions at trial.

Q. Okay. When you say these were documents that "we" refer to at trial, you're referring to yourself and attorneys representing the plaintiffs?

A. Yes, that's correct.

Q. Okay. And understanding that the purpose of today's deposition is focused specifically on the MDL, then you produced a report specific to the MDL on November 16, 2018, that we've marked as Exhibit 4, correct?

A. Yes.

Q. When did you begin work on the report that you produced specifically in the

MDL?

A. Sometime right after -- I would say early fall of 2018, sometime after this -- the supplemental report was filed. Probably right after that.

Q. Okay. So is it fair to say that you began work on your MDL report after completing the supplemental expert report that has been marked as Exhibit 3?

A. Yes, that's correct.

Q. Okay. Who was involved in the drafting of the report that's been identified as Exhibit 4?

MR. MEADOWS: Objection. Hang on a second.

Are you asking about communications between attorneys and Dr. Plunkett?

QUESTIONS BY MS. BRANSCOME:

Q. Dr. Plunkett, none of the questions I will ask you here today are intended to elicit information that's protected by the attorney-client privilege.

So setting that aside, anything that you understand to be privileged, I can

ask who the -- who was involved in the drafting of the report that was produced in the MDL?

MR. MEADOWS: Hold on just one second.

Ask the question one more time. I want to make sure we're not venturing into attorney work product realm here.

QUESTIONS BY MS. BRANSCOME:

Q. Dr. Plunkett, do you consider the report that you have issued in the MDL which is identified as Exhibit 4 to be attorney work product?

MR. MEADOWS: Objection. Don't answer that. That calls for a legal conclusion, and at this point I'm going to instruct you not to answer questions about how the report came into be.

MS. BRANSCOME: Are you instructing her to refuse to answer any questions that involve the development of her expert report?

MR. MEADOWS: I'm instructing

her not to answer your last question.

QUESTIONS BY MS. BRANSCOME:

Q. Are you following your attorney's instructions, Dr. Plunkett?

A. Yes.

MS. BRANSCOME: At this point I would like to go off the record, please.

VIDEOGRAPHER: Okay. We are going off the record at 9:30 a.m.

(Off the record at 9:30 a.m.)

VIDEOGRAPHER: We are back on the record at 9:32 a.m.

QUESTIONS BY MS. BRANSCOME:

Q. Dr. Plunkett, other than attorneys, if attorneys were involved -- I am not asking questions about that -- were there any individuals who assisted you in preparing the report that has been marked as Exhibit 4?

A. There was no one that actually assisted in writing the report. I do -- when I did my literature searches, I had my husband help me retrieve articles that I identified for retrieval, but certainly there was no -- he doesn't participate in the

actual review of articles or in drafting of the report. That's all my work.

Q. Okay. And when you say that your husband retrieved articles, was this simply -- what information did you provide him in order to enable him to retrieve a particular article?

A. So we use a service in Houston called Loansome Doc, which is affiliated with our local medical library system and also with the National Library of medicine and NIH libraries. So I give him an online search that I put into a clipboard. He takes that, makes the request or retrieves -- some of them will be free, and so he'll actually go to the websites for the -- and then put them into a folder for me.

So he does that physical part of it through the computer, but he doesn't -- he doesn't do the searches or decide which ones to retrieve. I do that.

Q. Okay. Did you have any discussions with your husband about the substantive content of the report that's identified as Exhibit 4?

A. No.

Q. Does he do any evaluation -- for example, if you were to provide him a search and it generates multiple documents by a given author, does he identify additional articles that you might want to consider?

A. Only -- he has done that, but only with the streams of letters to the editor. So I ask him always if I'm pulling an article. Happens a lot at the New England Journal of Medicine or some of the other medical journals where there's pretty active letter to the editor correspondence that happens.

So I always say to him, "If there's any citation to this through the letter to the editor comments, would you please retrieve those," and so he will do that search to look for that.

Q. Okay.

A. And I'm not sure that that happened in any of these articles, but I'm talking my general process that we use.

Q. Okay. In terms of the relationship of the three reports that have

been marked as Exhibits 2, 3 and 4 to each other, what is your -- what is your position with respect to opinions that you have stated or language you have used in Exhibits 2 and 3 that may not appear in Exhibit 4?

A. I don't think I understand what your -- what you mean by my position. Are you asking --

MS. PARFITT: And I'll object to that question.

THE WITNESS: Are you asking me to describe -- I mean, I could describe for you the overlap. I mean, there's not complete overlap. Is that what you're asking me or --

QUESTIONS BY MS. BRANSCOME:

Q. I am. Why don't you take a shot at it and then I may narrow my question, but I'm just trying to understand how the reports relate to one another.

MR. MEADOWS: Objection.

THE WITNESS: So they relate to each other, I would say, based on timing first, because obviously the first report was two years ago, and

then many more documents. So that's how the 1 and 2 relate -- or Exhibit 2 and 3 relate to each other.

In the MDL litigation, I was asked to address very specific topics and things because there's a -- it's a different -- I don't know all of them, but there's a different set of experts that work in different litigations.

So my role in the MDL, I believe, is set out based on this report, whereas in the original reports I may have had -- I did have a broader role in some of those cases.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. Can you describe for me your understanding of your role in the MDL?

A. It's my understanding that I have been asked to provide opinions related to the -- generally the toxicology of talcum powder products, including all the individual constituents that make up that product; to look historically back in time about what was known and when about the toxic effects of talc and different constituents within talc.

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And that was sort of the -- that's been -- I consider that sort of the meat of what I've been asked to do.

But separate from that, another part important part of my testimony or things I was asked to provide was an overview of the regulatory process for cosmetics and then the information that accumulated scientifically, how that related to what a company is required to do under the regulations in order to provide consumers with appropriate information about the safety of the product. So kind of the regulatory opinions, I guess you want to call it, that area.

I have sections on that, and I think you can see that by the different sections in my report where I set out different general topics.

And then I was also asked to address some of the issues related to how the information on the safety of talc has been disseminated publicly and also based on my review of different internal company documents, both from Johnson & Johnson -- or from Johnson & Johnson, Imerys, as well as

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the PCPC, which is the Personal Care Products Council, formerly known as the CTFA, to look at those interactions and how those companies set about to influence the process around the safety assessment of talc over the years. So different activities that happened with respect to the ISRTP meetings in the '90s, with respect to the NTP process at different points in time.

The CIR process, I think I cover, and I also talk a little bit about IARC, I believe, as well.

So the interactions of the industry with the science and then how that science ends up getting described within -- either to regulators or to bodies that are reviewing the science related to the products.

Q. You mentioned as one of the categories that you were asked to opine about in the MDL that you were looking to set about the influence that companies may have exerted over the regulatory process or PCPC.

When you began that analysis, did you start with the predicate belief that

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the companies had, in fact, influenced the regulators or PCPC?

MR. MEADOWS: Objection.

THE WITNESS: Not in my -- not when I first started this process. So that is -- those opinions actually go back into my original report. So that's not something, I don't believe, that was not covered in my original report or even in my supplemental report. I just have different -- some additional documents that I have reviewed.

QUESTIONS BY MS. BRANSCOME:

Q. Okay.

A. And this is something when I first evaluated the case and first started looking at the documents, those are opinions that I had formed based on my review.

Certainly by the time I drafted the MDL report, I think if you listened to my -- read my trial testimony, you understand I had those opinions at the time I started writing this report.

Q. Now, what I'd like to

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understand next is, are there -- of the topics that you just identified that you understand that you're offering opinions about in the MDL, which, if any, of those topics are in your view new as compared to the opinions that you have offered that are contained in Exhibits 2 and 3?

MS. PARFITT: Objection.

THE WITNESS: So I don't think any of the MDL opinions are new.

QUESTIONS BY MS. BRANSCOME:

Q. Okay.

A. I think that they may have -- they may -- they may cite to additional documents that haven't been cited to in the first two reports, but I believe there's a significant overlap even on the documents that are cited.

Q. And you mentioned that your role in the MDL is more narrow than the role you've served in other cases.

What topics have you opined about in other cases that you are not intending to opine about in the MDL?

A. So I am not doing general

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causation in the MDL, although I am indeed providing opinions on certain aspects of the cause and effect relationship such as -- you know, I talk about biologic plausibility, underlying knowledge about different toxicities of the compounds over time, but I'm not doing a full causation analysis in my MDL report, and hopefully you see that when you read the report.

Q. So as you sit here today, Dr. Plunkett, you are not intending to offer the opinion in the MDL that Johnson's baby powder causes ovarian cancer; is that correct?

A. Not in those words. I think if you read my report, I talk about the fact that Johnson -- it's my opinion that Johnson's baby powder increases the risk of cancer -- ovarian cancer, which is a different assessment than the way you stated it.

Q. All right. And it is -- as you sit here today, Dr. Plunkett, it is your understanding that you are not being offered to give a, as you termed it, a general

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causation opinion in the MDL, correct?

A. That's my understanding, yes.

Q. Now, you mentioned that the analysis as to whether a substance increases the risk of a particular outcome is different than a causation analysis.

Can you explain to me what you meant by that?

A. So I discussed this yesterday in my deposition. There's -- there's a process called risk assessment. Sometime -- in the area of consumer products you can also refer to it as safety assessment. And then there's the process of what I call general causation analysis, or full causation analysis.

So even though the types of information that are considered may overlap between those two, the outcome or the statements or the -- the way you go about assessing the information is a bit different.

Q. Explain to me how they're different.

A. So in a risk assessment, the process starts with setting out some basic

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principles of, first, is there a hazard, is the first step. Is there a hazard that would be relevant to human health.

Then looking at the data and determining whether that -- that body of data allows you to either quantify risk in some way or to qualitatively shows you that there's a change in risk based on exposure to the product.

So your statement may be as simple as there's an increased risk, or you can take data in a risk assessment and do a quantification such as in a -- a cancer risk assessment based on an animal data set. You might actually calculate a cancer potency factor, for example. Those kinds of things. That's another application of risk assessment. Same basic process but focusing just, for example, on one study.

My human health risk assessment or safety assessment, like the causation analysis, does look across all kinds of data, but my goal was not to analyze the data under the Hill considerations, which is what I would typically do, in order to go through

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the process of making that final opinion that indeed baby powder -- exposure to baby powder through genital application is a cause of ovarian cancer in women. That's -- to me, that's a different way to go about thinking about the question that you have to answer.

And also the -- some of the data that you evaluate is evaluated a bit differently. So, for example, in my increase -- in my issue of increased risk, I use the epidemiology as supporting evidence, but I'm really focused on -- on -- more on the underlying sort of the biologic information that we have that identifies hazard and risk. So looking at the animal data, the exposure potential for the product, and then using that along with what we know with the human experience to characterize risk.

Q. Is there a different level of certainty required to render a causation opinion than to render an opinion that there's an increased risk?

A. I don't know that I'd describe it quite that way but -- because to me it's a

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different process. I certainly have to be just as certain about what I say about risk when I do a risk assessment as I do about -- as I do when I'm doing a causation analysis.

I don't -- maybe you mean something else, so maybe you can -- I mean, I -- I certainly use the same basic standards in my mind, how I weigh evidence to do the different processes, but I go about them in a little bit different way when I do a risk assessment versus -- versus a causation analysis.

Q. In your view, does the strength of the evidence have to be greater in order to determine that an agent causes a disease, for example, than it does simply to say that an agent increases the risk of a particular outcome?

MR. MEADOWS: Objection.

THE WITNESS: I don't think I've ever thought about it that way. I would say to you that strength -- the strength of the association is a consideration under Hill that you apply the epidemiology data mainly, so

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that is a different consideration under causation than you do -- as you would do it in a risk assessment.

But the strength of the evidence, it's still a judgment based on your experience and training as far as whether or not there is enough information to be able to say that you believe that there is -- enough information to say that the risk is increased based on that exposure and those conditions and whatever the toxicity profile of that compound is.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. We'll get into this more a little bit later, but when you say that a risk is increased, is there a threshold level of increase that you need to see in order to render an opinion in a court of law that an agent increases the risk of a particular outcome?

MR. MEADOWS: Objection.

THE WITNESS: So I need you to define what you mean by threshold. Are you asking me a specific

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statistical test you would apply, or what are you asking?

QUESTIONS BY MS. BRANSCOME:

Q. So understanding that for the most part if you're looking at statistical significance, you're looking whether the confidence interval crosses 1.

Are you following?

A. Yes, I know that, yeah.

Q. All right. And so when you're evaluating, though, whether a particular substance, in this case Johnson's baby powder, increases the risk of an outcome, again, in this case ovarian cancer, would it be sufficient for you if that increase was .01 percent, for example?

MR. MEADOWS: Objection.

THE WITNESS: That doesn't make sense to me, an increase of .01 percent, but maybe I can answer it this way for you based on what you've laid out there.

Certainly when I do a risk assessment and I make it -- if I'm going to make the conclusion that I

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believe that it's my opinion to a reasonable degree of scientific certainty that exposure to baby powder in women increases the risk of cancer, I'm having to rely on -- I do rely on data that allows me to draw conclusions because either there's a statistical significant finding found or the -- there's a consistency among the pattern of the data that shows there's information that fits together consistently. And maybe -- you want me to explain what I mean by that? No?

Whereas I think what you're asking is when an epidemiologist applies -- looks at a body of -- in a causation analysis looks at a body -- and I do this, too -- looks at a body of epidemiological studies and you weight the studies, obviously you're weighting the studies differently based on whether they have shown statistical significance or not, right?

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And it isn't that it's a one to one. If you have one positive and one negative, that isn't how you may decide to finally weight that evidence, but certainly you have to consider whether or not what was seen or reported is showing you something reliable -- or you can make a statement reliably about whether or not that finding was biologically significant. And biologically significant would typically be linked to a finding that has statistical significance in an epi study unless the study was not designed to be able to answer the question properly.

So -- and I've discussed that a little bit yesterday with Mr. Smith on the issue of power to detect. So that's something you do consider in epi.

But, yes, statistical significance certainly goes into your weight of the evidence there.

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QUESTIONS BY MS. BRANSCOME:

Q. Okay. You talked about you're intending to offer an opinion with respect to what a company is required to do under the regulations; is that correct?

A. Yes.

Q. Okay. What regulations are you specifically referring to?

A. So cosmetic regulations that exist within -- so it's the entire process as I describe how cosmetic -- what -- are cosmetics subject to regulation by FDA? Yes. What are the types of things that companies have to do before they're marketed, what does the company have to do once the product is on the market, those kinds of things.

Q. Have you ever worked directly for any regulatory agency?

A. No, I have not.

Q. And suffice it to say you have never been in a decision-making position within a regulatory agency, correct?

A. That's correct, I have not.

Q. Have you ever been in a decision-making position with respect to a company evaluating compliance with FDA regulations with respect to cosmetics?

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A. Yes.

Q. Okay. What is your experience with respect to that?

A. So that's -- one of the clients that I currently work for where I am asked to provide input on advertising, promotion and labeling of some of the products and then also some of the ingredients that are being promoted for use to -- to produce cosmetic products. So it's the idea of providing that advice over my understanding of the regulations what can be said and can't be said about certain ingredients.

This company is involved in making both ingredients but also some finished products now based on -- it's a large company that owns a lot of little subsidiaries.

Q. My question, though, Dr. Plunkett, was, have you ever been in a decision-making position for a company evaluating compliance with FDA regulations with respect to cosmetics?

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MS. PARFITT: Objection. Asked and answered.

THE WITNESS: So that's what I'm saying. They're relying on my input to make a decision on what will go in the materials.

QUESTIONS BY MS. BRANSCOME:

Q. Do you have decision-making authority within that company or, as you described it, are you providing advice and input?

A. I'm providing advice, but the things I'm advising on are the things that happened. So in other words, they don't have anybody in the company that understands the process of what they can say. So I -- I advise them that you need to remove this language or that this is more appropriate language. They make those changes, and then that is what is done.

So I agree, I'm not an employee of that company. I am a consultant working with the company, but it is a little different than some of the work that I do where I -- what I -- the advice that I'm

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giving is actually something that I know actually happened. Sometimes you give advice to companies, but it doesn't -- we have no idea whether the company actually follows our advice.

Q. My question is slightly different, Dr. Plunkett.

If you were to give advice to the company that you've referenced as having experience with cosmetic regulation compliance that that company chose not to follow, that company has the ability to ignore your advice, correct?

A. Yes, I would imagine that they could do that.

Q. Okay. Have you ever drafted regulations that relate to cosmetics?

A. Actually drafted a regulation? No, I have not.

Q. All right. You reference in your report language out of 21 CFR 740.1, and specifically -- you reference it in a few places. And I can direct you specifically to paragraph 22 in Exhibit 4.

A. Yes. I'm there.

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Q. All right. And do you see here you have replicated language from 21 CFR 740.1 that reads, "The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product"?

Do you see that?

A. Yes.

Q. And you added emphasis on particular portions of this sentence, correct?

A. Yes, I did that, exactly.

Q. All right. Now there's a clause in this sentence that states, "Whenever necessary or appropriate."

Do you see that?

A. Yes.

Q. You did not emphasize that language; is that correct?

A. That's correct, I did not.

Q. What is your understanding as -- what you describe as an FDA regulatory specialist of the meaning of "whenever necessary or appropriate" in 21 CFR 740.1?

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A. So it's -- first off, you would use the common English language definition. I don't believe that those -- I haven't seen a definition separate within the regulations. Sometimes there will be.

So based on that and my experience and the looking into what others have described about this, this is the idea of considering how the product is used, is one of the -- one of the concerns that you have, and whether or not the -- based on how the product is used and how the product is being sold, that in order to prevent a health hazard, a warning hazard -- a warning statement would be needed.

Q. Can you cite to me any language within the regulation or even supporting documentation, a comment, something of that nature, that would define "whenever necessary or appropriate" with respect to how the product is used?

MS. PARFITT: Objection.

THE WITNESS: I don't think I understand your question.

Are you asking me to cite to a

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reference or a part of the regulation where they explain it, or what are you asking me? Guidance document or --

QUESTIONS BY MS. BRANSCOME:

Q. Yes. Can you point me to anything other than your personal view of the interpretation of this language that would tie the requirement "whenever necessary or appropriate" to how a product is used?

MS. PARFITT: Objection. Form.

THE WITNESS: I'll have to go look for you whether there's a guidance that states it that way. This is based on my experience in dealing with the products in the past.

I think that's also consistent with what is described, I would say to you, within -- it's consistent -- what I'm describing to you, it's consistent as well with how the CIR standard for safety assessment is done, looking at the issue of the -- of the -- of the use.

QUESTIONS BY MS. BRANSCOME:

Q. When you say that you're basing

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your interpretation of the clause "whenever necessary or appropriate" on your personal experience, can you point me to something specific?

MS. PARFITT: Objection.

THE WITNESS: Are you asking me -- are you asking me if I've ever had a company that I worked for that that particular clause in here was extremely important to how we interpreted it? I don't think I can point you to that. I don't recall ever having to do that specifically.

Or is it something different you're asking me?

QUESTIONS BY MS. BRANSCOME:

Q. Dr. Plunkett, I asked you what your basis was for interpreting the language "whenever necessary or appropriate" means that it's related to how a product is being used, and the answer that you provided was that it was based off of your personal experience.

So I'm asking you, what is that personal experience that gives you the basis

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for that specific interpretation?

MR. MEADOWS: Objection.

MS. PARFITT: Objection.

THE WITNESS: So it's in my experience in dealing with companies that make products and what types of warnings are put or not put onto -- or not -- or on labeling. So I don't know how else to answer it other than that.

I can go back and look at the guidance documents to see if that is described in another way, but I don't recall that.

QUESTIONS BY MS. BRANSCOME:

Q. So as you sit here today, you're not able to provide me either with a third-party document or an independent document interpreting "whenever necessary or appropriate" as you've suggested today, nor can you give me specific example from your personal experience; is that correct?

MS. PARFITT: Objection.

THE WITNESS: Well, I certainly -- I'd have to go back and

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look at my documents in order -- the first part of your question, I'd have to go back and look. Off the top of my head, I can't tell what I would point you to.

On the second one, I think I was telling you, is I don't -- I've never -- I don't have a client that I've worked for where that part of the language was the only issue that I had to deal with when I'm looking at whether or not the product needs a warning or not.

So typically -- I'm just telling you that when I have looked at labeling for products and looked at the issue of does it need a warning statement, when I'm reading it as "whenever necessary or appropriate," I'm looking at whether or not the ingredient that I'm concerned about within the product, how that is used or what the exposure pattern would be, route of exposure, how those things might relate to how I would assess the

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safety issue at hand. And so that's what I'm trying to tell you.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. You also have -- changing topics a little bit, in this -- in your report marked as Exhibit 4, if you could turn to paragraph 10.

On page 7, you state on the first paragraph on page 7, "In other instances I have directed others to perform searches on my behalf," and this is with respect to identifying documents for review in forming your opinions.

What did you mean by that?

A. So in addition to doing my own searches of the database, sometimes I -- I have called the attorney's office and asked them to -- to do a search for certain things that I'm looking for to add to. So in other words, I have a document I've identified. I'm looking for other documents like that in the large millions and millions of documents that are available. And so sometimes I will ask attorneys to do -- to look in the database for other documents like the ones

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that I've identified.
Q. And without getting into anything that would be -- that would call for information protected by the attorney/client privilege or attorney work product, what percentage of the overall searches for relevant documents from these particular databases that are discussed in paragraph 10 would you say that you have done yourself as opposed to directed others to do?
A. Well, initially when I first started searching, those were my own searches exclusively. I would say that more recently, in the last year, since I haven't added any real new areas but there's new documents that have become available, so anything -- any of the searches probably in the last year that dealt with new discovery that was produced, I would have asked the attorneys to do some of the searching in that for me. Like I'm looking for documents that are similar to this document that I cited in my original report around this same frame that may be discussing this same topic area.
So in the last year I have

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asked them to do that more than I have done it, but initially it was what I did initially.
Q. Okay. Do you keep any records of the various document searches either that you have performed or you have asked to be performed?
A. No, I don't. My record would be -- the initial -- the record would have been what I listed in my reliance list for you in the initial report, but since then it would just be what is going to be changing within my reliance list, looking at additional documents. That's the only way I could identify for you. That would be my -- my trail to know what was new and what was not.
Q. My question is slightly different. Understanding that you have provided to some extent a record of the documents, my question is: Do you have any type of record for the nature of the searches, what it was that you set out to identify in the database and how did you go about finding those documents?

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A. So that might cross over into work product because it's not my database, but I don't know how to answer that. I mean, I'm sure -- it's very possible that in the database you can track that, but I -- I don't know.
MR. MEADOWS: Okay.
THE WITNESS: I don't have anything saved on my computer that way, but when you go to the database itself, it's possible you could track that. I just don't have a record on my computer in my office.
QUESTIONS BY MS. BRANSCOME:
Q. When you made the decision at some point in time -- it may have been even prior to you issuing your first report -- that you wanted to look at company documents, did you set out specific categories of documents that you wanted to review?
A. Not so much categories but key words. So -- and areas. I guess areas is what I -- yes, I was focusing, for example, in my initial report on documents that described what was known -- what the company

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was discussing about cancer, ovarian cancer, cancer generally. So that was a key word used.
And then I also was linking that in different searches with different time periods such as the NTP review process and dates. You can, you know, narrow down by dates or by the CIR process. Those kinds of things.
So I did start with that, trying to understand what -- what is -- what was in the company files or in the files I had access to, the database, that dealt with those kinds of things because those aren't things that I could get to publicly. Obviously in the literature. So I had to -- if I wanted to understand what the company knew, I had to go into their database to find out, you know, what they knew -- what they knew or were discussing over time about the ovarian cancer issue or about asbestos in talc or about CIR process, things like that.
Q. Using the reports that you have produced, Exhibits 2, 3 and 4, really, and the full -- the entirety of the materials

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that you have produced in the MDL, is there any way that someone reviewing those documents, and those documents alone, could replicate the searches that you have conducted in the company databases?

MR. MEADOWS: Objection.

THE WITNESS: I don't know. That's a good question. I've never thought about whether you could replicate or not.

I mean, I think I've told you what I did. My strategy was to focus on topic areas. So I think you might -- by topic areas, if you use the same kinds of topics areas as described, I think you would come up with documents that -- what it focused down to.

For example, I also would sometimes, as linking those words, I might put in J&J documents only or Imerys documents only, because the database has a variety -- and the PCPC. There's some different ways by the Bates numbers that you can

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segregate documents as well. But I don't know other than that. That's all I can tell you.

QUESTIONS BY MS. BRANSCOME:

Q. You would agree with me that your report does not contain a complete explanation of the process by which you identify company documents to review, correct?

A. I haven't laid out my search structure, that is true.

Q. All right. Now, the articles that you have listed on your reliance list, have you read each and every one of those articles?

A. Unfortunately, yes, over time I have. Some of them I have only read parts of them. For example, if I started reading a document and I felt that it was something I pulled that really wasn't directly on point for an area I'm covering, I may not have read every word, but certainly I have been through each of those, yes.

Q. Are there any articles in your reliance list, that you maintained on your

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reliance list, that you read, but then once you started reading decided weren't relevant to the opinions that you were offering?

A. I would have to look to answer that for you. I don't know. If you want me to do that, I'd have to look.

Q. I ask you more as a process matter.

A. Oh.

Q. If you pull an article and you start reading it and you realize that it is not relevant to the opinions that you offered in this case, the example that you just gave, is it something that you would include in your reliance list?

A. Yes, I -- I have given you everything I retrieved. So if I retrieved it, you would have, yes, absolutely.

Q. Okay. So it's fair to say of the articles that are on your reliance list, you could not say as you sit here today that you have read each and every word of each and every one of them, correct?

A. That's correct. And I could probably tell you -- I could give you a

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little guidance in that possibly if I went to my list, I could try to pull some out that I recognize, but that's all I would be able to do for you.

Q. Okay. How did you go about identifying what articles you wanted to review in forming your opinions in the MDL?

A. So first off, I went back to what I already had. So my MDL report is a -- is a compilation of a lot of material that's in my first few reports. That was the basis for some of the things that went into it.

So I didn't -- I did do, though, a updating on literature searches for the MDL report, looking for anything new, for example, in the area, especially the area of cancer data or reports of dealing with ovarian cancer either -- or any articles dealing with the link between inflammation and cancer, ovarian cancer, generally. That's one of the areas I updated looking at.

And then I did -- I don't think I did any large, new searches, however, because honestly the areas covered here are a little narrower than what was covered here.

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I don't believe that there was any from the published -- the publicly available medical literature. There wasn't a need to do a whole new area of search. It was more updating the things that I've done in the past.

So it's a real easy search to update because you can just put in talc and cancer and just look at -- get lots, but you can then just start chronologically and look what was published in the last year, for example.

Q. Okay. Earlier when we were discussing the fact that you in some instances have asked your husband to pull articles, have you maintained any records of the searches that you have done with respect to scientific literature, including the searches that you have asked your husband to do?

A. I have not. It's possible that there are records on billing from the library that tells you how many I ordered at different times, but that is the only records, because we do have to pay the

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library for the retrieval.

Q. Okay. And if I understood what you said earlier correctly, you indicated that any article you have ever pulled for review, you have listed on your reliance list; is that correct?

A. Yes. And when I -- and let's just make sure we're talking about the same thing.

So, you know, in my reports I typically have articles cited in the report separate from the reliance list. So I'm talking about the reliance list, right? Okay.

So -- because I do -- I do usually -- I don't know whether I did that in this report, but I typically have a list of articles cited at the back called references, that is, things that you're actually seeing in the report body, and then there should be a separate reliance list sent to you as an appendix. I don't know what the appendix was.

Q. Well, so then let's clarify that. So, Dr. Plunkett, when you're

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referring to the reliance list, are you referring to the list of articles that begins on page 40 of Exhibit 4, or is there a separate document?

A. There's a separate document. So it -- that's -- I usually call reliance list the separate document. I call this references cited. So I apologize for that confusion.

So these, I have read every word. If it's in my reference list, those are not an issue of not having read every word, and these should all be cited somewhere in the report.

Q. Okay. If you could turn to paragraph 21 in your initial report.

A. Yes, I'm there.

Q. Okay. So we're looking at paragraph 21 in Exhibit 2. This is on page 10.

Do you see there is a sentence here that refers to -- it's referring generally to the topic of the ability of talc to migrate from the site of application to the ovaries.

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Do you see that?

A. Yes.

Q. And then the next sentence states, "This issue was discussed by scientific and regulatory bodies that review the toxicokinetics of talc."

Do you see that?

A. Yes.

Q. And in parentheses it identified EPA 1992, IARC 2010, and CIR 2013.

Do you see that?

A. Yes.

Q. Okay. And then if you could turn to Exhibit 4, which is your MDL report, at paragraph 43. It's on page 28.

Are you with me?

A. Yes, I am.

Q. You see that the exact same sentence appears -- well, not the exact same. It's been slightly modified to combine the first two sentences. But here you cite only to EPA 1992 and IARC 2010.

Why did you remove CIR 2013?

A. Because of my further evaluation since my initial report in 2016 of

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the process that was involved in the drafting of the CIR and the actual production of the report.
Q. Is it your position that the migration of talc was not evaluated as part of CIR 2013?
A. No. That's not my position, no.
Q. Okay. And so would the sentence that's contained in paragraph 43 in Exhibit 4, which is your MDL report, if you cited to CIR 2013 in the parenthetical there, would that not be an accurate citation?
A. I believe it would not be an accurate citation because I have formed opinions about the reliability of that document at this point in time.
So it has to do with -- I'm citing to authorities here that I believe are reliable as far as the discussion that I see, and it's a different -- I have a different opinion now about the CIR report, which I lay out in pretty detail, I think.
In fact, if you go to my section following this now in -- you'll

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understand one of the issues I had was the -- the difference in the evidence that was actually available once you dig into it a little further versus what they actually reviewed. That's one of the issues.
Q. And I'll follow up with some more questions about the CIR, but my question here is, the sentence in your report simply states, "The migration of talc internally after perineal application was discussed by scientific and regulatory bodies that review the toxicokinetics of talc."
Would it be inaccurate to say that as part of the CIR 2013 process that body did, in fact, discuss the migration of talc internally after perineal application?
A. It is true that they did discuss it. I just have an issue with the reliability of their findings.
Q. And so you made the decision to just remove it from the citation; is that correct?
A. Yes, at this point -- at this point, at this report, that's exactly right.
Q. All right. And then I had

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another question. In paragraph 43, you added two studies from your prior -- that were -- that did not appear in your prior report, and it was Gardner 1981 and Edelstam 1997. This related to animal studies showing that in some species talc can migrate from the lower to the upper genital tract?
A. Yes.
Q. Okay. Were those studies that you were aware of before drafting your prior reports?
A. I don't know that they -- I can't answer that without looking at my reliance materials for the original report. I did identify additional articles, and there's also additional articles cited here in earlier paragraph 43 that were not cited in my original report as well. I don't think I had the -- the Kunz article then cited. I'd have to go back and look.
So it's possible that they were in my -- when I say my reliance materials, my original report also had a larger list of literature I didn't cite. So I'd have to look. I can't tell you whether I had them or

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I did not.
Q. Okay. With respect to Edelstam 1997 study, do you happen to know the title of that article? Even an approximation would work.
A. It'll be -- should be back here. Just a second. If it's not here, that's a mistake.
Oh, here it is. "Retrograde migration of starch in the genital tract of rabbits."
Q. So you are citing that article for the proposition that animal studies have demonstrated that talc can migrate from the lower to upper genital tract?
A. Yes, I'm citing it because it's relevant to the issue of particle migration, which talc is a particle. So, yes, that's correct.
Q. Okay. But that study did not specifically deal with talc migration, correct?
A. No. Well, it -- it's relevant to talc migration, but you're exactly right, they looked at the starch migration, yes. Or

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particles that were starch, yes.
Q. We'll cover this in more detail, but is it your opinion that all particles have similar characteristics with respect to their ability to migrate in the genital tract?
A. It's my -- I don't know if I'd state it quite that way. What I would say is that the evidence shows that particles generally have the ability to move up the reproductive tract in women, yes, and that if a particle is one that is similar to talc or some of the other ones where the information has been collected, I would characterize that as being within that, quote/unquote, relevance of particles.
That doesn't mean all particles, but certainly in the ones that I have looked at and the data I've relied upon, there's a variety of different types of particles or substances that have been studied and shown to be able to migrate.
Q. So let's take Edelstam 1997 as an example.
Did you do any analysis that

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you can point me to that establishes that starch would have a similar migration pattern as talc?
A. So I would say that the paper itself shows -- talks about the movement of starch, but are you asking something different?
Are you asking me have I done a specific analysis of any differences that may occur between the migration pattern of starch and talc? Is that what you're asking me?
Q. That is what I'm asking you.
A. I certainly didn't do an in-depth analysis of the differences, no, but based upon my review of the literature, I believe that that paper is relevant to the overall question of migration of particulate through the reproductive tract, including particles of talc.
Q. Regardless of whether or not it was an in-depth analysis, can you point me to anything other than just your belief after having read these articles that starch and talc would have similar migratory characteristics in the human or animal

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genital tract?
MS. PARFITT: Objection.
THE WITNESS: Again, I haven't done an in-depth analysis. I mean, as a toxicologist, there are differences between starch and talc, absolutely. For example, starch would -- I would expect to be more easily solubilized within fluids, and so that could affect the ability of them to actually not migrate as well as a talc particle, which would be less soluble than the starch would be.
And there's -- I even -- there's a paper I have in here, and I can look for it if you want, that talks about that difference, and it's one of the issues of cornstarch versus talc, on whether or not you would expect to get the long-term chronic responses with the difference between those two substances.
So I do think there's difference, absolutely, as toxicologists generally. And the only

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reason I'm citing this paper is because I'm trying to be complete about people that have looked at this issue. And certainly it was a study that looked at this issue and talks about the movement.
But I wouldn't expect starch and the talc to have the same liabilities, and I also wouldn't expect them to move exactly the same speed maybe. That's very true.
QUESTIONS BY MS. BRANSCOME:
Q. So you would agree with me that Edelstam is not a study demonstrating that talc can migrate from the lower to upper genital tract, correct?
MS. PARFITT: Objection. Form.
THE WITNESS: I wouldn't say it that way. What I would say instead is that Edelstam is a study that forms the overall weight of the evidence for the ethics -- for the studies that are available that address the issue of migration, but certainly it is not studying talc. So I don't disagree

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with you there.
Unfortunately, the majority of the information that I have relied upon, and others such as the FDA in making their statements about migration, is not all directed studies just to talc. It's looking at the issue of particle movement.
QUESTIONS BY MS. BRANSCOME:
Q. Now, in terms of doing your risk assessment -- well, let me get back. We covered this earlier, and I want to return to it for a moment. Just to confirm: For your work in the MDL, you did not do a Bradford Hill analysis, correct?
A. I did not sit down and do a Bradford Hill analysis when I started writing this report. I have done a Bradford Hill analysis in the past, which is in my original reports, but I certainly did not redo a Bradford Hill when I sat down to draft my MDL report, that is true.
Q. Okay. Let me be more precise.
In the report that you have produced that contains a description of your

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opinions in the MDL, you have not set forth a Bradford Hill analysis in that document which is identified as Exhibit 4, correct?
A. That is true, yes.
MS. PARFITT: Objection.
QUESTIONS BY MS. BRANSCOME:
Q. And in fact, the paragraph that you -- or paragraphs that you have in your prior reports that reference a Bradford Hill analysis, those have not -- those have actually not been replicated in any form in Exhibit 4, correct?
A. Yes, because, again, it was not my role to do general cause.
Q. Okay. So then when we look at the methodology that you employed in reaching your opinions that are contained here in Exhibit 4, how would you characterize the methodology?
A. As I have in the report. I talk about it being a risk assessment or a safety assessment, that you could use those terms interchangeably here. And then I've also used a weight of the evidence as a tool to go through the different steps of the risk

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assessment.
Q. Okay. What publication would you direct me to that has used the same methodology that you have used to reach your opinions in Exhibit 4?
A. I think I cite you to -- cite you to some of those. You could -- well, the directly relevant one would be looking at the chapter on risk -- toxicology in the reference manual on scientific evidence.
You can also go to the NRC report where they -- it lays out the different steps that you use when you kind of break data apart into exposure versus response information.
And then I cite to -- there are some guidance documents that I cite to, and this is in paragraph 13. And I'd have to pull them out again to tell you which ones relate to different pieces because some of these are -- some of these documents are specific to only, for example, maybe one part of what I did.
But certainly the risk assessment process at IARC is -- they do what

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I call a hazard assessment. They identify hazard and they couldn't quantify risk, but the steps they go through are essentially the same types of steps that I went through as far as gathering data on not just response but also the potential for exposure and how that relates to the response.
And then also the data that I've collected on the biologic effects of talc, toxicology of talc, are also discussed within that document as well.
Q. Okay. Focusing specifically on the weight of the evidence tool, as you describe it, is there a particular document or publication that I would go to that could lay out the same process that you used for how you weighted certain pieces of evidence?
A. So the documents that I've cited for you in paragraph 13 talk about what weight of the evidence is generally, but if you read what it is, it's essentially a process that each scientist brings their experience, training and judgment to.
So I try to lay out for you in my discussion of the literature my thought

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process as I review each piece of information, and that is what you do as part of weight of the evidence. You gather all of the relevant information that you can find that address the question you're trying to answer, and since I'm looking at both exposure and response, I gather different pools of information.

Q. You would agree that there are ways to do a weight of the evidence assessment of published literature that assign, for example, quantitative values to particular pieces of evidence, correct?

A. Certain individuals have put together, but there's no one general accepted process that everyone uses. So I -- that's the issue. Again, there are certain -- certain cases where I've seen that done, and then there are many -- most cases that it's not what's done.

Q. Okay.

A. Another body, by the way, that I -- it's new. It's not in paragraph 13. I just want to make sure I tell you that so we're clear. If you look at the Canadian

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document, they also -- in fact, a lot of what they have, you'll see the same literature described within my assessment as well.

Q. So using the Canadian assessment as an example, for instance, in that assessment there were actually values assigned to particular pieces of literature, correct?

A. Mainly the epidemiological literature, that is true. Again, but I'm not doing causation, so I didn't approach it that way.

But certainly if you look at what I did, it's consistent with that because I talk about the differences between the limitations of a case-control versus a prospective study. I talk about both the positives and the negatives within the database, but I don't lay it out in a table like they do. But it's certainly the same basic process.

I was actually quite surprised at how similar the database of information that they reviewed was to what I honed in on as well.

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Q. Okay. As you were forming your opinions, Dr. Plunkett, about whether or not there is a risk associated with the use of Johnson's baby powder with respect to ovarian cancer, how do you keep track of the pieces of scientific evidence that you have reviewed and the respective weight that you give to them?

Presumably you did not read everything in one day, for example?

A. No. That's correct. So I typically will -- I typically will save the papers -- when I read the papers, I will often highlight in yellow information that I think is going to -- will be extremely relevant. I don't put notes on the document. I highlight in yellow on the PDF file to use that to write.

And I also start drafting report very early, which then gets overwritten and actually ends up looking like an outline that eventually becomes the report.

So one of the ways I keep track of things is I may put a paragraph name that

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I know I'm going to write, such as exposure migration, and then I -- as I'm reading a paper, I'll type in a paper -- the ones that I believe are important to my overall assessment. So I will do that as I'm -- as I'm going through the evidence.

So that's one of the tools I use, but I don't keep notes. I just kind of use that as a living document that eventually becomes a report.

Q. Do your opinions ever change as you read additional pieces of scientific evidence?

A. Yes, it does. It may change. And it often -- often the changes, though, are not that I believe -- with the exception of epidemiology. In other areas. Epidemiology is a little bit different issue when you're reviewing studies.

But on toxicology I always start with reviews and regulatory authorities, looking at what others have said generally about the toxicology. And so even though I may refine opinions differently or I might change, I certainly wouldn't agree to

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work on a project to start with if my initial reviews on hazard, for example, didn't convince me that I believe that there is a hazard. But you refine it from there. That's exactly right.

So there are cases, however, where I'm asked to work on a project where there is no review or regulatory authority or any kind of assessment over a period of years, and in those cases there are times when I start working on a project and I stop and say, "I can't do this." Because that happens, yes.

So opinions do change sometimes based on review of additional information.

Q. Is there any documentation that you've produced either in your report or otherwise in the MDL that would allow someone reviewing the material to understand the order in which you reviewed materials or the specific weight that you assign them?

A. So order of review, no. I don't think you would know that other than -- you will note order of review if you look at the differences in the literature cited in my

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original report versus in the MDL.

So in my original reliance list, if there were documents that weren't there and they're now here, obviously that tells you it was a review.

On the issue of a -- of the weight of the evidence process, the only answer I can give you for that is that articles that I believe are -- are reliable, are relevant and are -- those are kind of the -- you look at the reliability of the studies, whether they're peer-reviewed or not or if they have proper controls put into place, things like that, whether or not the -- they're relevant to the question at hand. That you can get from looking at how I discuss them in the document. But certainly there's no, like, summary of that.

But certainly -- I think you understand -- you should understand when you read my report what weight I'm giving based on how I'm describing those -- those materials. I mean, it's --

Q. Well, for example, you do have different studies that you've identified in

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your report that have been criticized by others at some point in time, correct?

A. Yes, that's true.

Q. Okay. Now, in some instances you state that you then give little weight to those studies, correct?

A. Yes.

Q. But in other instances you find the criticized study to be helpful and informative, correct?

A. That's true. Because, again, judgment -- as anybody does weight of the evidence, different scientists can have different judgment.

Mainly, I think, when I look at the differences in that -- in that regard, I think you should pay attention to what the person is. So as a toxicologist, I may view a certain type of -- piece of data very differently than an epidemiologist may view it, as far as the reliability or the relevance, because we're coming at it from a different training and experience and judgment -- set of judgment on what is important to a toxicologist when I'm talking

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about risk versus how an epidemiologist might talk about risk.

Q. Could two different toxicologists review the same piece of literature and give it very different weight?

A. I don't know about different weight, but they certainly -- I know people come to different conclusions based on their overall assessments. That happens, definitely. I mean, there are always going to be individuals that look at things differently.

I know in this case there are people -- I've seen defense experts that reports in -- not in the MDL but in other cases, where people disagree with some of my opinions, and I disagree with their opinions. That happens.

Q. Okay. And so if I were -- well, let me just ask something. You have not provided any sort of quantitative assessment of the weight that you gave different pieces of evidence that you cite in forming your opinions in the MDL, correct?

MS. PARFITT: Objection.

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Misstates her testimony.
MR. MEADOWS: Objection.
THE WITNESS: So I don't report for you a table where I quantify that, that is correct, but certainly that is -- because, again, based upon looking at the way that I was trained and the documents that I'm talking -- I'm pointing you to to describe how to do weight of the evidence, it is not -- it is not a numerical exercise, how many here, how many there, this one gets 5 points because of this or 6 points because of this.
It's more an issue, again, of judgment. It's the idea of looking across all of the available information and determining whether or not, based on that, it's your opinion that there -- that, for example, talc -- talc's toxicity profile includes cancer. That's one of the judgments -- weight of the evidence judgments you make, for example.

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QUESTIONS BY MS. BRANSCOME:
Q. So -- but, Dr. Plunkett, just to be clear, you do not provide a numerical value to the particular pieces of evidence that you have considered as part of your weight of the evidence assessment in the MDL, correct?
MS. PARFITT: Objection. Form.
THE WITNESS: So I do not provide a numerical value as you see it laid out, for example, in the Canadian table, but certainly I do judge articles that I include in my weight of the evidence based on a system that includes different considerations such as -- like I said, peer-reviewed or not, that makes an issue.
Whether or not the study that's being reported is the only one -- the first or is this something that is -- that is describing an assessment that's been done by someone else and so you see a repetition or a consistency among the studies that

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you're looking at.
The robustness of the data. For example, the NTP GLP quality animal study, very high quality in the weight of the evidence. And I talked to you about that. In fact, it -- even though people criticize that study, that study is very valuable for looking at biologic changes that are consistent with a carcinogenic mechanism being initiated.
So even though you may say that you can't quantify risk from that animal study as far as calculating a cancer potency factor, what you can do is use that study of high quality to make judgments within a weight of the evidence for risk.
QUESTIONS BY MS. BRANSCOME:
Q. Dr. Plunkett, you understand I have seven hours today, and I -- while I'm very interested in the answers that you give, if we could just -- we will get to things like NTP when we get there, if you could just attempt to answer the question that I've

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asked.
I simply asked the question: Are there numerical values assigned to the particular pieces of evidence that you have considered as part of your weight of the evidence assessment in reaching your opinions in the MDL; yes or no?
A. And I said to you, not in the way that it's done -- I assume you're referring to something like what was done -- what's in the Canadian epidemiology table. I have not done that, no.
Q. Okay.
A. That's exactly right.
Q. Have you provided a qualitative chart, for example, of the evidence that you have considered in forming your opinions in the MDL?
MS. PARFITT: Objection. Form.
THE WITNESS: I don't know what you mean by qualitative chart. I certainly have -- I certainly, I believe, have given you qualitative descriptions of my weight within my discussions of each study, yes, I have

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done that.
QUESTIONS BY MS. BRANSCOME:
Q. You mention in response to the prior question that you have a system for weighting the pieces of evidence that you have reviewed.
Can you point me to paragraphs in your report marked Exhibit 4 that would outline in detail the system that you used to apply different weight analysis to different pieces of evidence?
MS. PARFITT: Objection. Form.
THE WITNESS: And I think I answered that, that there's no system written down by anyone. But what there is, instead, is if you read these -- if you read these descriptions of use of weight of the evidence that I've cited in paragraph 13 as well as the discussion of methodology in the Canadian document, that is consistent with what I do. It's the idea that you start with a literature search for peer-reviewed, publicly available

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information. You look at the quality of the studies, the statistically significant findings. Those are all things that are discussed within these documents I'm pointing you to.
QUESTIONS BY MS. BRANSCOME:
Q. Now, you --
A. But it's -- it's -- I don't know of anyone who has written down a specific system that applies in all circumstances, no.
Q. Okay. Have you written down a system that applies specifically in this case?
A. I think I have tried to do that for you when I describe what I did.
Q. Okay. You just referenced the fact that your system can be found in the Canadian document.
You agree that the Canadian analysis was actually published or produced after you had completed your report in the MDL, correct?
MS. PARFITT: Objection. Form.
THE WITNESS: Certainly it was

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published afterwards, and what I thought I said to you was that if you look at that document -- it's not in paragraph 13, but if you look at that document, it lays out a process. And I wouldn't call it a system. It's a process. It's a process by which you screen information for relevance to the question being asked and how, then, based on that, you look at characteristics of that information such as -- and I tried to give you some of those.
And I've said this before in depositions in these cases. You know, you look at the issue of whether or not the study was peer-reviewed, whether or not there was statistically -- statistical significance or at least statistics applied to the data. What was the quality of the study as far as the size in order to be able to answer the question being asked. Those are the kinds of things that you look at.

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And then also the question -- when you're looking at a specific question, you may pull in -- like you asked me about the starch particle. You may pull in things that you give less weight because obviously that's not just talc, that's starch, and you have to consider that. So that is part of the process.
QUESTIONS BY MS. BRANSCOME:
Q. Dr. Plunkett, the question I asked you simply was: The paper that you reference that contains some detail about the Canadian analysis, that was published after you completed your report that's marked here as Exhibit 4; is that correct?
MR. MEADOWS: Objection.
THE WITNESS: Yes, and I believe I answered that at the start. I usually try to answer your question, and then I try to explain further some details I think are important context on my answer.
QUESTIONS BY MS. BRANSCOME:
Q. I understand that,

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Dr. Plunkett. You have given many depositions. You understand I can ask you for more detail if that would be helpful to me.

If you could, just focus on the question that I asked, and we can explore additional areas if that's something I'm interested in doing.

Okay?

MR. MEADOWS: Objection.

She's --

MS. BOCKUS: Break?

MR. MEADOWS: After I finish my objection.

She's going to answer the question as thoroughly as she feels like she needs to answer the question based on the way you ask it.

Want to take a break now?

MS. BRANSCOME: We can go off the record.

VIDEOGRAPHER: We're going off the record at 10:41 a.m.

(Off the record at 10:41 a.m.)

VIDEOGRAPHER: We are back on

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the record at 10:56 a.m.

QUESTIONS BY MS. BRANSCOME:

Q. All right. Dr. Plunkett, we started talking a little bit about the CIR analysis that was done in 2013.

Am I correct you no longer consider that reliable? Is that your opinion?

A. Yes.

Q. Okay. And you identify in your report marked as Exhibit 4, I believe it's paragraph 56?

A. Yes, that's correct. And I think I talked about it later on as well, but definitely I do here.

Q. Okay. And in paragraph 56, you state that the CIR panel failed to account for all the studies that informed on the issue of migration of particles such as talc upwards through the reproductive tract.

Is that your opinion?

A. Yes.

Q. Okay. And then you state that because of that you assign, quote, little weight to the conclusions reached by the CIR

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panel; is that correct?

A. Yes.

Q. And so is it your view that a study or an analysis that reaches a particular conclusion should be assigned little weight if it fails to consider all relevant scientific evidence to the issue that it's evaluating?

MS. PARFITT: Objection.

THE WITNESS: I think it depends on the situation, but that could be the case, yes. It depends on -- on the -- depends on -- I think it would depend on each case, the question being asked, and what was omitted. But, yes, I think it could.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. And in this situation you identify -- I believe you claimed that eight human studies were not considered by the CIR 2013 panel; is that correct?

A. Let me look at the number, but that sounds about right. Yes.

Q. All right. And returning, actually, to your prior answer, you said that

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the failure to consider all relevant scientific evidence on a topic would lead you to assign little weight to a particular conclusion. You said that that could happen.

Under what circumstances would you assign a conclusion little weight for failing to consider what you consider to be all relevant pieces of scientific literature?

A. Well, I think it depends -- well, the reason I specifically addressed that in this case is because that was -- the conclusions about migration is the main reason why the CIR panel then draws additional conclusions later on.

So my issue is, migration was key to what -- the decisions they made about the safety issues of talc. And so in that particular case, this -- this failure to consider all the evidence was extremely important, in my view, and I gave it little weight.

There might be a situation where some -- for example, you may only look at six or eight studies, even though there may be dozens out there. You may have a

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reason for why you only looked at six or eight, or it may be -- and as a result you may lay that out and, therefore, you may still give weight to conclusions drawn. Or it may be that the six or eight are -- studies that you discuss are not -- the weight is not affected by what you've omitted.

I believe that the weight is affected by what is omitted when you look at some of the articles being review articles, which give you an understanding of what was generally accepted within the scientific community when you get to reviews, those kinds of things. So it really is a case-by-case basis.

But certainly I do believe that it is possible that in another circumstance where things are omitted you would come to the same conclusion, that you give those conclusions less weight.

Q. Is there a way, if someone were try to replicate the weighting of particular evidence based upon your process, for them to know whether or not the omission of a

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citation of certain studies means that a study should be given little weight or whether it wouldn't affect the weighting of that scientific article?

MS. PARFITT: Objection. Form.

THE WITNESS: So I think this is the issue of judgment, training and experiencing that is applied to all such assessments, and this is why different scientists may come to different conclusions. But certainly it is -- it was important to my assessment on this issue because of the prominent role that the CIR report gives to their conclusions here for why they then drew conclusions about safety. And so that link was extremely important.

MS. BRANSCOME: Can we pause for just a moment?

VIDEOGRAPHER: We are going off the record at 11:00 a.m.

(Off the record at 11:00 a.m.)

VIDEOGRAPHER: We are back on the record at 11:01 a.m.

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QUESTIONS BY MS. BRANSCOME:

Q. Okay. Of the eight studies that you identify on page 37 of your report that you contend the CIR panel did not account for, do any of those eight studies specifically discuss the migration of talc in human subjects?

A. No, I don't believe they do, but there are a couple of these studies that I found to be extremely important if you want me to explain that to you.

Q. Do you break out in your report in any other paragraphs which of these eight articles you consider to be extremely important?

And if you could just point me to paragraph numbers, that's good enough if you have, in fact, broken them out.

A. I have. I -- this whole section I break -- I talk about each one individually. So I think you can tell by what I read -- what I'm discussing what I thought was important and informative about each of those.

Q. Do you rank the eight studies

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in any way by their importance to you?

A. Not with any numerical rank, no, but certainly I think I do that for you when I talk about the studies. I give you an understanding of ones that I think are particularly informative and ones that are not.

So, for example, I weight the human data -- I think I tell you that -- more than the animal data because of the differences between the reproductive tracts of humans versus animals generally, upright versus -- upright and habits and things that humans do that relate to insertions in and out of the reproductive tract, I guess is a nice way to describe it, versus an animal, that those can have, and then also the differences between animals and humans in terms of bursal sac around the ovary, those kinds of things.

So I do -- that -- I guess that ranking I do give you here. I tell you that I think these -- I think that the most relevant are going to be the human studies versus the animal studies.

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Q. Right.
So my question specifically is, where would you point me to in your report to understand the weight that you gave each of these particular eight studies?
A. At my descriptions of those studies and what I describe. That's all I can tell you.
Q. And I'm just asking, Dr. Plunkett, can you point me in the report to where that discussion takes place?
A. It takes place -- I have a discussion for each study, and I would -- and if you read what I say about each study, I try to go through what the strengths and weaknesses of those studies are.
And so those -- that would be, let's see -- you want me to give you the starting paragraph?
Q. So, for example, Parmley and Woodruff. Can you point me to where in your report you discuss Parmley and Woodruff, such that I can understand the weight that you gave that particular study?
A. So the year of it is...

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So I think I discuss it in paragraph 44, and so I describe for you what important information is in there, which is the information that I take as forming part of my weight of the evidence.
So one of the most important things is what -- they have a figure they show, and they're showing -- which is one of the unique figures in all of the published literature. But it talks about the differences between the female reproductive tract and the male reproductive tract, and it shows the actual -- it talks about a discussion of movement from substance in the environment through -- into the vagina, into the fallopian tubes. So it's a paper that addresses that very specific issue.
Q. So my question to you, though, is, where do you have a discussion of the weight that you give to these particular articles?
A. So the discussion of the weight has to do with the information described. I don't give them a numerical ranking. I told you that.

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So what I do is, when I'm discussing about these -- all of these papers here contribute to my weight of the evidence. And if it's a human study, I'm giving those more weight than I'm giving animal studies. And that's described.
And then within papers I'm pulling out information that contributes to what I think is important about what the study says, and that -- and the importance of what is described within the study contributes to my weight.
And I don't know how else to describe it to you. That is the process that scientists go through when they evaluate data.
Q. And so my question to you: Earlier you said of these eight studies, some of them were particularly important to you.
How would I, using only what's written in your report, understand which of those eight studies was of particular importance to you?
A. So it would have to do with what I discuss about the study. So I'm

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telling you, when I -- if you look through this entire section, this is the Parmley and Woodruff paper. It is important because it addresses the specific issue of movement of environmental substances from the outside to the inside. So I'm giving that importance in my evaluation because of what that author is actually discussing.
I don't know how else to describe that. I apologize. I mean, to me, weight of the evidence is a process that scientists use bringing their training and experience and judgment, and it's not a numerical process across the board, it just is not, based on the way weight of the evidence is used within science.
Q. Now, Dr. Plunkett, though, you would acknowledge that if you wanted to assign numerical values to the studies, that has been something that has been done by other authors and other authors on whom you rely, correct?
MS. PARFITT: Objection. Form.
THE WITNESS: I don't believe that's true. I'll need to look -- I

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don't believe that's true with respect to the biological information. I believe it may be true with respect to the epidemiology studies.

You want me to look real quick to confirm that? I can do that really quick, but...

QUESTIONS BY MS. BRANSCOME:

Q. I'm simply saying, could you assign a numerical value if you chose to do so?

MR. MEADOWS: Objection. Objection. Form.

THE WITNESS: And I'm -- what I'm trying to say to you is I think that I -- that there is no one set of rules that you would assign in order to do that for all the types of studies that you weigh.

I would agree that I have seen it routinely done -- well, not routinely, but I've seen it done within the epidemiological community when they go through the epi data. But not -- it's not something that

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I've seen done when you talk about weight of the evidence as part of a human health risk assessment. That is not something that scientists typically do as far as giving numerical rankings.

QUESTIONS BY MS. BRANSCOME:

Q. You're familiar with the National Cancer Institute, correct?

A. Yes, I am.

Q. All right. They are considered to be the nation's leader in cancer research, correct?

MS. PARFITT: Objection to form.

THE WITNESS: The National Cancer Institute?

Yes, they are. I don't know if they're "the" leading, but they're one of the leading, that's true.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. And you're familiar with publications that they issue called physician data queries?

A. Yes, I am.

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Q. All right. And you are aware that there is, in fact -- called PDQs, correct?

A. That's the abbreviation, yes.

Q. Right. And you're aware that the National Cancer Institute has in fact published a PDQ that addresses a potential connection between talc and ovarian cancer, correct?

A. I'm aware of several that have been done over the years, but, yes, I'm aware of that.

Q. And have you reviewed those?

A. Yes, I have.

Q. Are they listed on your reliance list?

A. No, but they're listed within the materials as discussed within my depositions, and I thought -- and my testimony. I thought that was part of my reliance list. I believe that it -- it was in my reliance list, is encompassing all of the testimony as well as the actual documents. Maybe I'm mistaken, but that was my understanding.

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Q. Okay. If they are not on your reliance list, should they be?

A. I believe that they are on my reliance list by it having been pointed to as part of the testimony that I have given and the documents that I have relied upon during testimony.

Q. Okay. And you are aware that they have issued a PDQ that -- on the website as of today, correct?

A. I haven't looked today, so I'm sure -- but I know that -- I don't believe it has been removed, so I believe that there is something there, yes.

Q. All right. And what is your understanding of the position stated in the PDQ with respect to a possible link between talc and ovarian cancer?

A. So I'd have to look at the one today to tell you what it says, but it's evolved over time and it's changed over time, and I have specific opinions that I've expressed at trial about that issue.

Do you want me to go into that details or I mean --

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Q. I'm not asking about your opinions about what their position is. I'm simply asking you, Dr. Plunkett, the most recent NCI PDQ that you have reviewed, what is the position that the National Cancer Institute has taken with respect to the relationship between talc and ovarian cancer?

A. So I would want to pull it out to give you the specific statement of their position, but their position has changed such that later in time they've weakened the link -- their statements about the link between ovarian cancer and genital talc use.

So it used to be seen as a cause, and now I believe it's not seen as a cause. I don't know the exact language, though. I'd have to look at it as -- maybe risk factor is the better word to use.

And I need to look at the most recent one. And that would be the best way. Let's just see what it says.

Q. Okay. 'Cause is it your position as you sit here today that the National Cancer Institute has ever issued a statement that talc causes ovarian cancer?

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A. I believe it was listed as a risk factor for ovarian cancer in the older PDQs.

(Plunkett Exhibit 7 marked for identification.)

QUESTIONS BY MS. BRANSCOME:

Q. I do have a copy here. Just for the sake of the record, we will mark this as Plunkett Deposition Exhibit Number 7.

Handing a copy to you, Dr. Plunkett, do you recognize the document that I just handed you that's marked as Exhibit 7?

MR. LOCKE: What's the date of that?

MS. BRANSCOME: This was printed on December 14, 2018.

THE WITNESS: It's -- the updated date is June 22, 2018, if that helps.

MR. LOCKE: Yes, thank you.

THE WITNESS: I have seen this one, yes.

QUESTIONS BY MS. BRANSCOME:

Q. All right. And you can review

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any -- whatever portion of this is helpful to you.

And then if you could answer my question, Dr. Plunkett, of what is the position as stated in Deposition Exhibit Number 7 of the National Cancer Institute with respect to the relationship between talc and ovarian cancer?

A. So I would be looking at the section on page 12 of 18, and maybe you're looking somewhere else, but that's where they actually talk about perineal talc exposure. And it's under the section where they have now moved into factors with an adequate evidence of an association and they describe it here. So they're calling it an association where the weight of the evidence is not adequate to support that association.

Q. All right. And so the first sentence of the section under perineal talc exposure states, "The weight of the evidence does not support an association between perineal talc exposure and an increased risk of ovarian cancer."

Did I read that correctly?

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A. You did read that correctly.

Q. All right. And it indicates that "results from case-control and cohort studies are inconsistent."

Did I read that correctly, Dr. Plunkett?

A. You did.

Q. And the question that I would ask simply is, do you discuss the National Cancer Institute PDQ in the report that you've issued in the MDL, which is identified as Exhibit 4?

A. I don't specifically discuss this document, no, I do not.

Q. Okay. And you understand that the NCI PDQ did a weight of the evidence analysis that followed a formal evidence ranking system, correct?

MS. PARFITT: Objection.

THE WITNESS: So I -- it's not laid out here, but they do have a process they use.

Is that what you're asking me?

QUESTIONS BY MS. BRANSCOME:

Q. Yes.

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A. Yes. And again, they're ranking the epidemiological data, and so I understand that that is there, yes.
Q. Now, you've said a few times that you could qualitative -- you could give a quantitative weight to an epidemiological study, somehow suggesting that it is different from other types of studies.
What is it about a toxicological study, for example, that would prevent someone from giving a quantitative weight in a weight of the evidence analysis?
A. Because it is just what is typically done and not done. There are certain practices within the community, what is kind of -- I would say that scientists use routinely, or scientists have used. Not all scientists give numerical rankings to epidemiological data either, because even within a Bradford Hill assessment, when you use the considerations, there's no requirement for ranking studies in order to meet the requirements of use of that methodology.
Q. Okay.

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A. But I have seen it done in the epidemiology community, and that is the most common place I see it. I do not see other toxicologists that are assessing animal studies and in vitro studies doing it that same way.
When you do a human health risk assessment, that isn't routine practice to do numerical rankings on studies.
Q. Okay.
A. At least in my experience and in my training, and I was trained in the use of risk assessment by one of the individuals who actually invented the process.
Q. Okay. Okay. But do you consider the epidemiological evidence as part of your risk assessment in the MDL?
A. I do, because I'm looking at it in the context of what is out there and what's available. I don't always have human data when I do risk assessments, but in this one I do. So I do consider them, yes.
Q. Okay. Did anything prevent you from doing a quantitative assessment of the weight that you were giving different pieces

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of epidemiological evidence?
A. If by -- you mean prevent, was someone stopping me from doing that, no. But if you ask what would be standard practice based on my experience, I would not be doing that.
Q. Has anyone -- and I'm not referring in this case to any attorneys. But has anyone reviewed your -- the weighting that you gave specific pieces of evidence as essentially a form of a peer review process?
A. If by that you mean have I submitted my opinions for publication, no, I have not done that. Part of -- that's partly driven by my understanding of the evidence that I reviewed, that some of it may not be something that I should be discussing necessarily in a public form outside of the cases I'm working in.
But certainly I have not submitted it for publication, if that's what you mean. No, I have not done that.
Q. Okay. Has the methodology that you have used in the MDL, has that been -- have you submitted any type of analysis using

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that methodology for publication even outside of particularly looking at Johnson's baby powder, for example?
A. Yes, in -- if you look at my publications that describe risk assessments that I have done. So the one that would come to -- to play that's similar as far as the scope of the weight of the evidence would -- at least with the animal and the in vitro studies, would be the paper that I published on copper, looking at the database of copper and identifying points of departure and target organs and risk -- risk issues based on copper use in humans, trying to set a -- understand what a safe exposure level could be to copper in water. And that was published -- that actually was one of the papers that's published with Dr. Krewski, who is one of the authors of this risk assessment in Canada.
Q. And is it your position that you follow the same methodology in what you've reported in the MDL with respect to Johnson's baby powder that you did in your analysis of copper?

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A. Yes, with the process of going through all of the publicly available information, putting it together based on its relevancy and reliability.

We did a process where we grouped it based on animal versus human, just like I've done here. And we call it the bins, but it's the same idea. I have a bin of human idea, I have a bin of animal data and a bin of in vitro data. And so, yes, the process was very, very similar.

Q. Okay. Returning back to some documents that you chose not to cite in your report, you do not discuss the Gonzales 2016 study in your report for the MDL, correct?

MS. PARFITT: Objection. Form.

THE WITNESS: I'll have to look. It is not cited in the reference list to my report, that is true. So that means it would not be mentioned specifically in the body of the report.

QUESTIONS BY MS. BRANSCOME:

Q. You're familiar with the Gonzalez 2016 study, correct?

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A. If you want me to talk about it, you'd have to pull it out for me, but I know the name, yes.

Q. Okay. And it was looking at an association between the perineal use of talc and ovarian cancer, correct?

A. That, I'd have to look at it to tell you. I believe it was a human study that would be consistent with that, but I need to pull it out to look at it.

Q. All right. Do you, as you sit here today, do you know why you did not discuss it in your report?

A. I wasn't doing a full causation analysis in this report, so as a result I'm not trying to characterize every piece of human data. But I certainly am looking at the consistency across the studies, and that's what I've done.

And I mention it here. I do think I mention here that there are studies that came to different conclusions than the ones that I'm specifically describing.

Q. Okay. And so why is it that -- why is it acceptable for you to choose not to

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include something like the Gonzales 2016 study, but yet you will disagree the 2013 -- the CIR 2013, you will give it little weight for not discussing particular studies?

A. So that's a very different exercise. You want me to explain my thinking on that? I can do that for you, but I believe that's apples and oranges question.

My reasons for giving little weight to the CIR overall assessment versus my weight or the assessment I make of an individual piece of data, that's different. And that's what you're describing for me.

And I believe Gonzales is in my overall reliance list, so I have read Gonzales. It is something that I have considered; it's not something that I've cited in my paragraphs. So it doesn't mean it didn't go into my weight of the evidence, because I do have it and I have reviewed it. I just don't recall the details on it.

Q. Is it your position as you sit here today that you know for sure that the CIR panel did not -- was not aware of or even considered any of the eight studies that you

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contend the omission of which makes it of little weight?

MS. PARFITT: Objection. Form.

THE WITNESS: I would say I'm 99.9 percent sure, based on the process that is -- that goes in. And if you want me to explain, I'll tell you why I feel that level of surety.

You know, I can always say that maybe there was someone that came to the panel that did a search on their own, but that is not what's done. The individuals that come to the panel are given a body of information provided to them in written form that they review. So it's not like they -- they have access to anything that isn't cited in the actual report.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. The eight articles that you discuss that are not mentioned in the CIR panel's work, they are publicly available pieces of scientific literature, correct?

A. Yes, which was why it's interesting to me that those were not grabbed

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and included within -- within the assessment done by the -- by the PCPC's group that handles CIR -- handled the CIR process here.

Q. Okay. We received just before your deposition, a few days in advance, a list of materials that have been added to your reliance list since you produced your report in this case.

Did you provide that list of materials to counsel to -- are you aware of the materials that were identified?

A. Yes, I am. They're ones that I have reviewed since my report and -- yes, which would have been, I believed, important for you to know about, because obviously you wouldn't know if I hadn't provided that to you, and fair game for you to ask me about.

Q. On that list was contained a number of news articles.

A. Uh-huh.

Q. Are news articles pieces of scientific information that you typically consider in performing a risk assessment?

A. No, they're not part of my risk assessment, but they -- but they were

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relevant to -- they were relevant to my overall assessment of the issue of what the company is doing with regard to public dissemination of information.

So it's not the risk assessment part. It's more on the issue of the -- when I talk about the different influences of the company on public dissemination of information, I went through the different specific issues. So this would be a specific issue related to a news report that someone comes out with, the Reuters report, and then looking at what the company is saying in addition to that.

So it's understanding -- for example, the documents that Reuters discusses, many of those I'm sure I have seen, although I don't have access to -- I wasn't able to go on websites and download everything that they cite. But certainly they looked familiar, some of the ones I did see.

So it's that issue of -- the last part of my report, I think. Want me to tell you the section? It would be in the

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section on the role of the industry in Section 7.

Q. Okay. So the newspaper articles are not something that you are considering as part of your analysis of whether there is a risk of ovarian cancer from Johnson's baby powder, correct?

A. No, that's a separate issue because it's not -- it's not scientific data, per se.

Q. Okay. All right. Now, if you could turn to paragraph 31 in your report.

Okay. You discuss the biological effects of talc in this paragraph and in others, correct?

A. Yes, I would call this my introductory paragraph to transition into a specific topic, yes.

Q. Okay. And you talk here about the structure and size of talc affecting its properties.

What do you mean by that?

A. So whether it's fibrous enough, platy, fibrous. Whether it is particle sizes of less than 10 microns, less than 5 microns,

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greater than 75 microns. There's different -- certain pieces of literature deal with different size ranges of talc. The smaller the size range, the more toxic it is, for example, to lung tissue; the more likely it is to be able to move, based upon the size, versus being engulfed by a macrophage if it's a larger particle, things like that.

Q. So focusing specifically on ovarian cancer, what role does size and structure of a talc particle play with respect to a risk of ovarian cancer in your opinion?

A. I don't think I formed a opinion that it has to be a specific size or structure, because the -- my opinions are related to the fact that we have a complex mixture of ingredients within the body powder, and my assessment's been on the overall consumer product, not on any one particular ingredient only within it.

So it's the idea of just understanding that size and structure of these particles are general principles that affect toxicology. So a larger particle or a

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fibrous particle may have a different tissue toxicity response than a smaller particle.
So in other words -- I think I discuss this later in a paragraph about pleurodesis, the idea that you can get acute versus chronic inflammation, or respiratory distress or not. So it's just this idea of a general principle that outlines how you would think about particles generally as a toxicologist.
Q. Well, okay. So you said that your assessment is based on the overall consumer product. That would be Johnson's baby powder or SHOWER TO SHOWER®, correct?
A. Yes.
Q. All right.
A. Or Shimmer. I think that's the other name. There's a third product.
Q. Okay. But my question to you is, you actually cite a number of pieces of literature in the section about the alleged toxicity of talc that don't relate to the overall consumer products at issue in this case, correct?
MS. PARFITT: Objection. Form.

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THE WITNESS: No, I would disagree with that when you use the word "relate." Relate to me means is it relevant to the assessment, and they are, even if they're not just on the finished product.
But if what you mean is that there are studies that did not test the consumer product but individual ingredients or -- that is true, yes, but all of that is relevant or relates to the overall risk assessment.
QUESTIONS BY MS. BRANSCOME:
Q. Okay. So given your view that information about the individual constituents is relevant to evaluating the overall toxicity of the ultimate consumer products, then my question to you is: How does the structure and size of the component talc particles play a role in toxicity with respect to ovarian cancer?
A. Just generally -- it's not just -- well, with respect to ovarian cancer, we start with irritation, inflammation potential. Size of particles and shape are

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known to affect tissue toxicity as far as adverse events like inflammation and/or irritation.
Q. Okay. So that's -- that's what I'm trying to understand in more detail.
What is your opinion with respect to -- let's take size to start with. Is there a particular size talc particle that is more or less likely to cause inflammation, in your opinion?
A. It depends whether you're talking about acute or chronic. I would say for acute inflammation the larger particles, such as some of the particle sizes that are used in the pleurodesis products, are more likely to initiate an acute inflammatory response due to the fact that they're large enough that the body will recognize them with a fairly robust foreign body response.
Q. What is your definition of large?
A. So the literature varies, but certainly particles that are above -- some of the literature talks about particles that are in the range of 25 to 75. Some of them talk

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about larger particles even than that.
It has to do with the fact that -- this is complicated by the fact that any consumer product -- or any talc sample will have a range of sizes because they don't select for one size. They select for smaller than. So a 200 mesh, a 400 mesh, that has do with what will filter through.
So pleurodesis, they try to avoid for those products the really small -- large amounts of less than 10 because that leads to respiratory distress, whereas many of the consumer talc products are using much smaller, finer particles to get that feel and performance they want from the consumer body powders.
Q. Have you reviewed -- focusing specific on Johnson & Johnson's products, have you reviewed the documents that relate to the specifications for the Johnson's products with respect to the size of the plate particles?
A. I have seen those, yes. I can't tell you what each of them says without pulling them out, but, yes, that is certainly

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documents I have seen and relied upon.
Q. Is it consistent with your understanding that it was Johnson & Johnson's intention to select large platy talc particles for its products?
MS. PARFITT: Objection to form.
QUESTIONS BY MS. BRANSCOME:
Q. Have you seen that in the documents?
A. I don't know that it's described quite that way, but they certainly were doing a 200 mesh selection. So -- for their body powders products. So -- and they were trying -- and they did make attempts to look for sources that were more platy talc than other forms, but that doesn't ensure that everything is platy talc.
Q. Are you familiar with the term "fines"?
A. Yes, generally, but I'm not -- but I'm not an expert in the processing of talc as far as how you would go about choosing an ore or a mine. There's others that will be addressing that. That's not my

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area.
Q. What is your understanding of the term "fines"?
A. My understanding of the term "fines" has to be looking for a sample or a group that has been processed such that it has certain characteristics.
Other than that, I would refer you to the individuals in litigation that are going to be dealing with the processing.
Q. Okay. Have you taken into account in your analysis in any way the beneficiation process that occurs between the time that the talc is mined and it ends up in one of the consumer products that is relevant to your analysis?
MR. MEADOWS: Objection.
THE WITNESS: So what do you mean by taking it into account? Am I aware that they have something that's in place for that? Yes.
But take into account, what do you mean by that?
QUESTIONS BY MS. BRANSCOME:
Q. Are you familiar with the

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effects that beneficiation can have on the level of the component -- the components in talc and what ultimately ends up in one of Johnson & Johnson's consumer products?
MR. MEADOWS: Objection.
THE WITNESS: So I'm not -- I'm not familiar with all the details, but I am familiar that it is a process they're using to attempt to result in a product that has characteristics that would be desirable for a consumer product.
Again, there is my understanding that others are going to be discussing the geology or the processing, and that is not something I'm looking at.
The literature as it relates to what has been tested in the public literature in particular, and that would be either an ingredient or a -- or a consumer product or a -- they may discuss exposure occupationally to mining or milling, which is -- which is an issue that you can consider when

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you're reviewing that literature as well.
QUESTIONS BY MS. BRANSCOME:
Q. Okay. And so when you cite -- for example, you have a significant number of -- I'm trying to find the right paragraph.
You have a section in your report where you discuss a number of different articles that relate to talc, and in parentheses you identify that the talc source might be cosmetic, it might be industrial, things of that nature, correct?
A. Yes, I do that on purpose because I wanted -- I did look at the literature to understand what they were -- what they were -- what type of exposure they were describing.
Q. Okay. And so understanding that some of those products are not representative of what ultimately is in Johnson's baby powder, do you have anything in your report that explains how you did or did not give weight to those particular studies?
MS. PARFITT: Objection. Form.

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THE WITNESS: Let me look and see what I say.
If the question has to do with numerical rankings, no, I did not do that. But you're asking something else, right, broader than that, correct?
QUESTIONS BY MS. BRANSCOME:
Q. The question that I have is, how did -- is there somewhere in this report that I can understand the weight that you assigned to say a study that related to industrial talc as opposed to information about cosmetic talc, for example?
MR. MEADOWS: Objection.
THE WITNESS: So I -- I'm -- I believe I address that. I don't know it's exactly answering your question, but I lay out for you the characteristics of the literature in paragraph 37, and I point out that the scientific literature varies.
And the fact -- and I point -- and I admit -- I'm not admitting. I'm stating the fact that in some cases

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the authors will not describe it specifically as the type of talc, but just talc, whereas -- with no description of purity or state, for example. But in cases where the literature does, I did consider that in my weight of the evidence.
So, for example, when I -- when I lay it out here in these bullets where I'm putting for you tremolite mining industrial grade cosmetic, it certainly is something that I weighed. And obviously as much information as I can get on cosmetic-grade talc is going to be most important in the assessment, but that doesn't mean the other information isn't relevant.
You want me to explain why?
QUESTIONS BY MS. BRANSCOME:
Q. Well, so, for example, you describe the Dreessen article that related to trimellitic talc that's mined out of New York.
You would agree that trimellitic talc from New York is not

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something that ever ended up in Johnson's products, correct?
MR. MEADOWS: Objection.
THE WITNESS: I don't think I can answer that yes or no. I haven't done an assessment to see whether it ever ended up in the products. That's a different question.
I certainly am aware of the fact that was not a primary source of their talc, that is true. I do know that.
In other words, I don't have records from -- going back from 1894 on what the source of their talc was. So I can't tell you over time.
What I do know, what's been put into depositions and testimony of company employees more recently, where it's my understanding that the principal sources over the years were either the Vermont mine, the Italian mine or the Chinese mine. And there were different interruptions in time where different mines were used,

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depending on sourcing.
QUESTIONS BY MS. BRANSCOME:
Q. So as part of your expert analysis where you are evaluating articles that relate to different types of talc from different sources of talc, have you done an analysis of how those particular types of talc do or do not relate to what is in the consumer product manufactured by Johnson & Johnson?
MS. PARFITT: Objection. Form.
THE WITNESS: The first part of your question, again? I'm sorry.
MS. BRANSCOME: Would you read it back?
THE WITNESS: Could you read it back to me again? I didn't mean to wander, but the first few words I missed.
(Court Reporter read back question.)
THE WITNESS: Okay. So I certainly did, which is why I'm breaking this out here for you this way.

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So I am -- I am certainly recognizing, and I analyzed on the paper -- through the papers what type of product, if available, that the data is on.

But if you read my report in the process of risk assessment, all of these categories of papers are relevant to telling you something about what talc can do. And then when you talk about drawing final conclusions, I'm looking for information, if I can, and I have it, that is on point to the product that was sold.

So certainly the studies that give me information on cosmetic-grade talc are extremely important to my assessment, and they're ones that I've discussed or we've even used in trial before when we've talked about putting together a timeline.

That's what this is about, by the way. This discussion here, I'm starting to lay out what information

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was available over time, and that's simply what this is. It's a survey of the literature that talks about adverse effects of talc, and if I can, I separate it into different qualities or purities.

QUESTIONS BY MS. BRANSCOME:

Q. Dr. Plunkett, respectfully, I don't believe you answered my question.

Can you point me to anywhere in your expert report that's been produced in this MDL where you do an analysis of how the different talc types and sources that you are citing as support for the toxicity of talc generally relate to the products manufactured by Johnson & Johnson?

MR. MEADOWS: Objection.

THE WITNESS: So I don't know how else to answer that but to tell you I think that's what this whole section is about. I step you through -- I identify different types of evidence. I identify for you what was tested in those different pieces of evidence, and then I step through

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that to draw conclusions based upon what was available for me to assess.

QUESTIONS BY MS. BRANSCOME:

Q. Okay.

A. I don't know how else to answer it for you. That's what the section is meant to do, and that's why I broke it out that way. You know, I recognize that there is data on different things.

What's interesting about even the data on different things, there's a common mechanism that is involved with the type of tissue toxicity you get, and that's irritation and inflammation. Regardless of whether it is of a certain grade or not, you get certain types of adverse reactions. May be a more sustained reaction with a industrial grade versus cosmetic grade, but they all have the capability to produce that type of adverse effect.

Q. Dr. Plunkett, where can you point me to in your report that you discuss the weight that you give studies that relate to talc from New York as opposed to studies that relate to cosmetic talc that ultimately

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ended up in Johnson's baby powder?

MS. PARFITT: Objection. Form.

THE WITNESS: I've tried to answer that for you. The weight that I'm giving -- the weight that I'm giving is part of my assessment. So, again, I don't give numerical rankings. I've answered that for you. I don't do that.

What I instead do is I'm looking at everything that's relevant, everything that's available. I do categorize it, so I am selecting -- I am identifying or analyzing the information for what it describes. And then if you go further on down, I try to tell you what I think is important about that information.

The overall conclusions I'm drawing in the report, though, when I cite to specific studies in the risk assessment, the majority of those studies I believe that I'm citing for you, outside of notice, have to do with -- that's more of a warnings

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issue -- have to do with the issue of cosmetic talc. Because the human studies are describing cosmetic talc. The NTP studies is a pure talc. Many of the in vitro studies and other animal studies are looking at, quote/unquote, a talc that is not an industrial grade or from a mine that would have -- be looked at in that way. So --

QUESTIONS BY MS. BRANSCOME:

Q. You understand that there are different types of cosmetic talc, correct?

A. Yes, I am aware.

Q. And cosmetic talc can be mined from a number of different mines globally, correct?

A. That's correct.

Q. And some of the studies that you cite in your report are testing cosmetic talc from other consumer products, for example, Cashmere Bouquet, correct?

A. Some. The majority of them are not, but I would agree that some do, yes.

Q. Okay. Have you done an

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analysis of how the talc that is used in Cashmere Bouquet, for example, relates to the talc that is used in Johnson's baby powder?

Is that an analysis that you have done before relying on that information in your report?

MR. MEADOWS: Objection.

MS. PARFITT: Objection.

THE WITNESS: My analysis -- I did do an analysis to look at what was described, what products are described, but I certainly -- I certainly did not throw out studies that described Cashmere Bouquet because I would -- I still believe as a toxicologist and a risk assessor that those types of products are important to the overall weight of the evidence about the hazard and the risks posed by talc.

You know, I just -- I just -- I guess I disagree with you if you're saying they're irrelevant. I don't believe that they are.

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QUESTIONS BY MS. BRANSCOME:

Q. I was simply asking: Did you do an analysis that would allow you to compare the ingredients in another product, like consumer Cashmere Bouquet, before you rendered an opinion with respect to Johnson's baby powder based on tests of Cashmere Bouquet? Did you do that analysis?

MR. MEADOWS: Objection.

THE WITNESS: I do not have access to internal company documents for the manufacturers of Cashmere Bouquet, so I certainly couldn't do the analysis in the same way that I can do it here, where I can identify what Johnson & Johnson and Imerys describe as sources of the talc that was used for the Johnson & Johnson baby powder, without --

QUESTIONS BY MS. BRANSCOME:

Q. So you have no way of knowing one way or the other whether that talc is similar, correct?

MR. MEADOWS: Objection.

MS. PARFITT: Objection.

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THE WITNESS: Well, I think I do know it's similar, if you look on the bottle as far as what is described it being, but if you're asking me -- if you're asking did we fingerprint it to only a particular mine, this is the beauty of the data. The data shows that regardless of the type of product you're looking at, there's consistency across the study.

So -- but I did not try to segregate out studies that only dealt with Cashmere Bouquet, no, I did not do that.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. As you sit here today as a toxicologist, is it your position that industrial-grade talc that might contain up to 70 percent tremolite presents the same level of toxic effect as cosmetic talc that may contain no tremolite or tremolite at a very, very low level?

MS. PARFITT: Objection. Form.

THE WITNESS: I haven't formed that opinion, no.

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QUESTIONS BY MS. BRANSCOME:
Q. Okay. And so have you formed an opinion that I could find in your report that discusses in any way the relative toxicity of different types of talc?
A. That, you may find. I need to go back and look how I set it out, but I think I -- I talked with you about the difference between fibrous versus platy. I do discuss that.
And I talk about the problems when you have a complex mixture that has added to it things like asbestos and heavy metals, because I talk about the additivity issue that can come to play. So that -- in other words, increased risk when you have a complex mixture with additional components that all share the same toxic properties as far as target organs or types of effects or mechanisms that are triggered in the body. That's what I point you to.
I -- I don't -- that's the only way I can answer that for you, I think, based on what I know I have in here.
Q. Okay. You talk about the term

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"asbestiform talc."
You talk about asbestiform talc.
Are you familiar with that?
A. I do mention that in my report, yes.
Where are you?
Q. At paragraph 30. It's on page 19 of your report.
A. Yes, I'm here.
Q. Okay. And the first sentence in paragraph 30 you state, "In the published medical literature, there is often discussion of talc using terms such as fibrous talc, asbestiform talc, non-asbestiform talc or tremolite."
Do you see that?
A. Yes, I do.
Q. Okay. Is it your opinion that tremolite is a form of talc?
A. So tremolite is a -- is a -- is a type of fiber or a -- tremolite is a -- is a substance or a entity that has been identified as a specific morphology, I guess, identified characteristics of a -- it has

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identified characteristics.
There's -- within the asbestos -- the asbestos literature there's -- it's one of the forms -- forms of asbestos that's described. For example, in IARC, they describe all of the ones that have carcinogenic properties. It's one of them.
Within the literature within Johnson & Johnson's documents, there's tremolite discussed as -- I assume them referring to asbestos tremolite, asbestos in a tremolite characteristic. I have seen tremolite talc also mentioned in the literature.
If you want a specific discussion of each of those, again, there's -- I understand there's experts that are going to describe the distinguishing characteristics of each of those.
I'm only setting out this is what I have seen, talked about, in the literature.
Q. So you are not an expert on the differences between fibrous talc, asbestiform talc, non-asbestiform talc and tremolite as

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it relates to toxicity. Is that your opinion today?
A. No, that's not what I'm saying. I'm saying that if you want me to -- I'm -- if you want me to describe the characteristics and the morphology of each of those individually, that's something a geologist would do.
But certainly as far as the toxicity assessment I did, each of these types of -- each of these words, I guess, or names have been applied in the literature when they talk about toxicity of talc. Some of the literature talks about fibrous talc or just -- other literature just talks about talc. Some of it, for example, the IARC monographs, distinguish between asbestiform talc and non-asbestiform talc in their assessments of the cancer risk.
And then tremolite is discussed as a component of talc. And I have seen papers that talk about tremolite -- nontremolite talc or tremolite-containing talc. That's how you most often see it.
So it's the idea that it is a

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constituent of certain mines that -- and that's my understanding of it. But if you want -- and they all -- they all certainly do show that the toxicity can be affected, whether it's a fiber or a platy particle. So tremolite being a fiber would certainly affect my overall assessment of risk. The more tremolite that you would have would make -- would make it more likely to be reactive in terms of a foreign body response, depending on the size.

Q. What's your basis for saying that?

A. That's based on a fibrous form versus a platy particle form. That's the issue of -- I have that paragraph where I talk about what macrophages look for, can engulf or not engulf. So those are all things that are important to a toxicologist to understand exist.

But certainly within my assessment I have to include literature from all of those because of the fact that all of those are relevant to the toxicity profile, since I know that the cosmetic baby powders

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and the data I've seen shows detection of something called fibrous talc.

I see detection of tremolite within certain samples of baby powder.

And then I have just the general category of asbestiform versus non-asbestiform when I consider the way, for example, IARC has reviewed the carcinogenicity.

So those are -- those are terms that I'm laying out because I think they are something you need to understand exists in the literature.

Q. Okay. But I'm trying to understand, not helping me understand the literature. I'm trying to understand your opinions with respect to toxicity.

Is it, for example, your opinion that fibrous talc has the same toxic potential -- let's focus specifically with respect to ovarian cancer -- as tremolite?

A. I haven't formed that opinion, but, again, I would -- my opinion has been formed on the fact that we have complex mixture that includes all of these things.

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Q. Okay. And so when you're looking at a complex mixture, you would agree as a toxicologist it would be important to understand the constituent elements of that mixture, correct?

A. Yes, it is important to understand that this is -- what is in the mixture, and that's -- that's part of what I try to do.

Q. Okay. And it would be important before drawing conclusions from one study that might have different constituent components, it's important to understand the relative toxicity of individual constituent elements, correct?

A. Depends if you can or not. I mean, there's certain types of studies you can, where in the published literature that's been described. That's why I'm pointing this out. It's the idea that within the literature, when you go through, it's important to understand what you can say about the consistency across the literature where maybe different types of talc are discussed.

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And that's what I -- I think I lay out for you. I tell you there's consistency in certain toxic effects that are seen. Regardless of the form that you're looking at, talc has certain properties, and all of these things are -- been shown to be in the complex mixture, so I have -- as a result, all of that literature has relevance to at least the hazard part of my assessment, and certainly have relevance to -- when you want to talk about warning and the final risk assessment, they're definitely relevant, but certainly the -- when I go through this process, I am trying to focus as much as I can on a product that is most similar to the one I'm assessing.

So obviously that's why -- that's one of the reasons I do look at the human data, because the human data is involving a consumer product use, which is what I'm talking about here.

Q. Is it using specifically Johnson's baby powder?

A. Many of them are, yes.

Q. Okay.

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A. Based on my understanding of what I see discussed within the literature.
Q. Did you identify in your report specifically which report -- which studies have used a consumer product manufactured by Johnson & Johnson?
A. I haven't laid them out individually, no, but I am aware of discussions of this general issue within some of the documents I've seen, and essentially Johnson's body powders products were the overwhelming share of the market.
Q. But you would agree that studies that did not involve the consumer product manufactured by Johnson & Johnson should be given less weight when analyzing whether or not there are risks associated specifically with Johnson & Johnson's products?
MS. PARFITT: Objection. Form.
MR. MEADOWS: Objection.
THE WITNESS: It depends on the question being asked within the assessment, the risk assessment. It really does, I mean, because each of

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these studies brings a piece of evidence to the risk assessment.
And so the question is -- for each one, you consider it on a case-by-case basis. It is possible, yes, that you would give less weight. It's also possible that you would not, dependent upon what you know about that study and how it relates to other studies that are out there.
QUESTIONS BY MS. BRANSCOME:
Q. So methodologically, how would I understand from your report marked as Exhibit 4 under what circumstances to give a study that relates to, for example, industrial talc less weight than a study that actually used Johnson's baby powder?
MR. MEADOWS: Objection.
THE WITNESS: Well, I've tried to tell you that. That's what I said for you. That's why I am doing it. I certainly am trying to focus in on studies that deal with the consumer product.
But what I find when I look

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across the studies that are dealing with not the consumer product but other descriptions, there is a consistency in the types of effects you see.
And since I'm not quantifying the risk but identifying it as being increased or not, in other words, is it more likely than not that someone exposed in this way could be at a risk of ovarian cancer, that's what I'm talking about.
So again, it's -- if I was trying to identify differences in cancer potency factors for different types, then, yes, if I had an animal study on each of those, I could compare potency for cancer, but that hasn't been done.
QUESTIONS BY MS. BRANSCOME:
Q. Okay.
A. So instead, what I have to do is rely on what is available to me. And based on my judgment, that's how I review the studies.

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Q. And so for the opinions that you are offering in the MDL, you agree that you are not quantifying the risk associated with Johnson's baby powder, SHOWER TO SHOWER® or Shimmer with respect to the potential for causing ovarian cancer?
MS. PARFITT: Objection. Form.
THE WITNESS: In terms of a cancer potency factor, that is true, I am not. Instead, what I am doing is I am quantifying whether or not I believe that the risk is increased above a background risk.
That has to do with -- that's where I bring in, in my risk assessment, the human data, because the human data is showing statistically significant increases in risk in populations using the consumer product.
So I have a quantification where I'm using the word "increased," and I believe to a reasonable degree of medical certainty that indeed the risk is increased. So I'm quantifying

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in that way, but I'm not giving it a number. I'm not saying that the cancer potency factor is such that you increase the risk from one in a million to 10 in a million to 1 in a thousand. That I have not done because I don't have the data, the studies. The company has not done studies on each of these to allow me to do that.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. The reference that you made to the human data that you believe shows a statistically increased risk in populations using the consumer product, have -- which -- have you identified in your report which of those studies are specifically using a product that was manufactured by Johnson & Johnson?

A. I don't lay that out for my report, I do not, but certainly it is something that for some of the studies I believe you can -- you might be able to get some of that information from. But certainly I have not laid that out individually in my

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report, no.

Q. And you would agree that for some of those studies there is no information as to the specific type of consumer talc that the individuals who are being studied used, correct?

MS. PARFITT: Objection. Form.

THE WITNESS: I would agree that in some of those studies they're not saying, but that is why you look at the evidence overall.

And what's important to look at in terms of now -- if you wanted to go to Bradford Hill, that's why you look at things such as consistency. So what do the studies show. We see a certain level of increased risk across studies, regardless of who did the study or what population was being looked at.

So that's the best way I can answer that for you. That is -- that is part of the -- of the assessment that you look at.

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QUESTIONS BY MS. BRANSCOME:

Q. In reaching your opinion in the MDL that there is an increased risk above background of ovarian cancer from the use of products manufactured by Johnson & Johnson, have you made an attempt to identify specifically which studies, the human studies on which you rely, test or look at people who have used Johnson & Johnson's products?

MS. PARFITT: Objection. Form.

THE WITNESS: It's my -- my review of the study indicates that I would say for the vast majority of them you cannot do that.

But you can take what is reported and look at things such as market share and those kind of things to get an idea of what you believe the exposure would have been.

But certainly I have not -- I have not tried to apply some kind of a numerical value to how many people in the study may have used Johnson's baby powder or not, no, that has not been done. I don't think anybody -- any of

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the bodies that have looked at this have done that.

QUESTIONS BY MS. BRANSCOME:

Q. You have not done a market share analysis, correct?

A. No, I've seen this in documents only. I have not done my own. There are company documents that talk about their market share.

Q. Okay. Have you made an attempt to examine the levels of fibrous talc or asbestiform talc that are in different consumer products, aside from Johnson's baby powder or SHOWER TO SHOWER® or Shimmer?

A. So for that are you referring to things such as -- other types of cosmetics like foundations or lipsticks or --

Q. I'll rephrase.

Have you made any attempt to examine whether other cosmetic talc body powders have a different percentage of fibrous, or what you refer to as asbestiform talc, from the Johnson & Johnson products?

Have you done any analysis to make that comparison one way or the other?

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MS. PARFITT: Objection. Form.
THE WITNESS: I certainly haven't done -- I certainly didn't do a directed analysis to try to determine that, but there is information, I believe, in -- I think if you look at some of Dr. Longo's work, that may be there.
And I believe in Dr. Blount's published paper there may be a discussion of the type of powder product used, where she was looking for -- at least for asbestiform -- asbestos within the talc. It may be tremolite as well, but -- if you want me to look, I can do that. I just don't recall whether -- I think she did talk about sources of the talc, where it came from, so...
QUESTIONS BY MS. BRANSCOME:
Q. Okay. But as you sit here today, you can't point me to any analysis that you did or an analysis that you relied on that would relate different brands of cosmetic talc body powders with respect to

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their constituent components?
MS. PARFITT: Objection. Completely misstates her testimony. She mentioned Dr. Blount. She mentioned others.
THE WITNESS: So I think what I started with, I said I haven't done a directed analysis to try to determine specifically how this product versus this product versus this product may have looked over time, because I don't have access to a full data to do that.
But what I do have is data that has -- I do see published data, for example, Blount and maybe some of the other published studies, that looked at this issue, at least of asbestos presence in talc. And I believe Dr. Longo also had things that weren't just Johnson's. I believe he had Cashmere Bouquet, for example, samples in some of the things he looked at.
So I can point you to those things that I have reviewed, but I haven't -- there's nowhere in here

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that I state for you that it's my opinion that Cashmere Bouquet has this specific pattern of constituents as compared to Johnson & Johnson's. No, I have not done that.
QUESTIONS BY MS. BRANSCOME:
Q. Okay. And that would be true for any other brand of cosmetic talc, body powders, Jean Nate, Lily of the Valley, not just Cashmere Bouquet, correct?
MS. PARFITT: Objection.
THE WITNESS: That is correct, I don't have access to that information.
QUESTIONS BY MS. BRANSCOME:
Q. Have you done any analysis of the constituent components of talc and how they have changed even within Johnson's -- Johnson & Johnson's manufactured products, how the constituents of the consumer products may or may not have changed over time?
A. I've done some of that, yes, and I laid that out, I think, for you, when I talk about the differences in the products that are described within the documents, the

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company documents, from the '70s versus the '80s versus later on, as far as the changes that were made to specifications of the product, for example. That's something -- and I think I've talked about that a bit at trial as well.
Q. Okay. And is it your view that the risk potential for Johnson & Johnson's manufactured products have changed at all over time with respect to ovarian cancer?
MS. PARFITT: Objection.
THE WITNESS: I have not -- I have not attempted to differentiate a risk potential at only one point in time.
What I have done over points of time is looked at the issue of warnings and what should be warned about.
But my analysis related to the hazard or the risk assessment of the products is considering all of the available information, which would be all of that information over time.

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QUESTIONS BY MS. BRANSCOME:
Q. Okay. You talk about, in paragraph 35 primarily -- we'll talk about the fragrance components in more detail, but you talk about the idea of chemicals being a potential irritant.
Are you familiar with that?
A. Yes, that's correct.
Q. Is it your position that any product that contains chemicals that could be an irritant should be labeled with a health warning?
MS. PARFITT: Objection.
MR. MEADOWS: Okay.
THE WITNESS: I don't think that's -- no, I don't think I've formed that specific opinion.
But the opinion that I think I'm expressing here is that when you have a -- the information that I have, which unfortunately the company hasn't given us percentages or actual levels, instead, what I do as a toxicologist, I look at what is there. And when I see over a hundred chemicals there,

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that 70 percent of them have been linked as an irritant hazard, there is the issue of toxicological additivity to consider.
So certainly as a risk assessor, when I have that many potential sources of irritation as far as chemicals going into a complex mixture, certainly I think I have formed the opinion that I think that is something that needs to be considered when you're talking about providing information to consumers, yes.
QUESTIONS BY MS. BRANSCOME:
Q. As a toxicologist, would it be important to you to understand the exact percentages of all of the constituent components of, say, Johnson's baby powder, for example?
A. Are you talking about just the fragrance or are you talking about everything that's in it?
Q. Dr. Plunkett, you referenced the fact that the company has not provided

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you with specific percentages, and so I'm asking you, is that something that as a toxicologist would be important information to you?
A. Depends. Certainly with the fragrance -- and I'm talking about the conversation about this paragraph is focusing on the fragrance components.
So, yes, I mention that it would be nice to know, it would be good to know, if we could, exactly what was in there, because I could quantify the hazard or quantify the risk, actually. So instead, I have -- I identify it as a hazard, but I can't quantify it without those levels.
But does that change -- make a difference in the overall conclusions I draw? No, it doesn't affect the overall conclusions that I have drawn, but it adds that other piece of the puzzle that deals with the fact that we have a complex mixture that have a combination of ingredients that target irritation.
And irritation and the potential to produce an inflammatory

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response, in my -- if you've read my report, you understand that I think that's a key factor in increasing the risk for ovarian cancer.
Q. Understanding the percentages of the constituent components, is that limited only to fragrance, or would it also be important to understand the percentages for the heavy metals that you contend are in Johnson's baby powder?
A. So if I was trying to define the hazard of each component, I would certainly want one to know that. As a result, what I'm doing instead is looking at the complex mixture. In other words, this is a mixture of all these things.
I break out those individual components, or constituents, to tell you about the hazard that is brought to play or the toxicity profiles that exists. And what's important about that in my overall evaluation of the end product, which is what my risk assessment is based on, the end product, shows that I have multiple components with similar types of effects.

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And as a toxicologist, when you do that, that affects the conclusion that you can draw about a body of literature.

Q. Okay. You do understand that there is testing data available about the percentages of the constituent components with respect to heavy metals, et cetera, that have been in Johnson's baby powder over time, correct?

A. There is some information. Unfortunately, the information is not complete as to every lot or every sample, as far as what I have seen. And also, there's some -- some of the sampling is reported as more of a limit versus an actual quantification. So it depends upon which -- which result, study result or document, you're looking at.

There is some there, yes, and that's one of the reasons why I identified these as part of my risk assessment, because I look for a pattern of these metals that are known to carry a hazard and whether or not these are ones I'm seeing detected time and time again.

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Q. But you made no attempt to quantify the risk with respect to any of those components or use that data in any way, correct?

MS. PARFITT: Objection. Form.

THE WITNESS: No, I used that -- that data as part of -- my risk assessment as part of my hazard assessment, absolutely. It's part of the hazard assessment.

But as far as quantifying them individually, no. I am quantifying the risk and looking at the risk of the entire product, not of just one individual component of the product.

QUESTIONS BY MS. BRANSCOME:

Q. Well, we already discussed you're not quantifying the risk with respect to the entire product, correct?

A. Well, I'm quantifying it in terms of an increase above background, which I'm not giving you a -- I told you I wasn't giving you a cancer potency factor. That is true. That I am not doing.

But I am quantifying it by

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using a word such as an increase -- an increased risk.

Is that a specific number? Am I telling you that it's increased by two times or four times or six times? No. The data available did not allow us to do that, with the exception of the epidemiological data. And the epidemiological data can show you that in that piece of evidence there appears to be a 30 percent increased risk above background.

Q. Did you make an attempt to quantify the risk with the data that you had available to you with respect to the final consumer product?

A. I could not, based on the data I had, because I didn't have a well-controlled animal study to be able to pull that out that way.

Instead, what I -- in this type of weight of the evidence, you look at what you might be able to quantify based on the human data. And certainly the human data showing the statistically significant consistent findings across studies for that

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30 percent increased risk, that is part of my overall weight of the evidence for me making the statement the risk is increased.

But you'll notice I don't say increased risk of 30 percent, because I don't believe that I can state that with certainty in the way I do a risk assessment. But certainly as any one individual -- any one individual piece of evidence or any one body, like the epi data, others have made -- other bodies who have looked at the -- talked about the consistency of the increased risk signal in the epi studies as being in the range of 30 percent.

Q. Okay. But you would agree that based on the methodology that you applied in this case, you could not say to a reasonable degree of scientific certainty that there is an increased risk of, for example, 30 percent with respect to use of Johnson's baby powder and ovarian cancer, correct?

MR. MEADOWS: Objection.

THE WITNESS: I have not done that. And I'm not saying that somebody else couldn't do that. I

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have not -- I have not chosen to do that based on my evaluation of the data.
QUESTIONS BY MS. BRANSCOME:
Q. And the same would be true if I asked that question and substituted any particular number, a 10 percent increased risk, a 20 percent increased risk, correct?
MR. MEADOWS: Objection.
THE WITNESS: I haven't given a specific number in my final opinions, that is true.
QUESTIONS BY MS. BRANSCOME:
Q. Okay.
A. I've tried to explain to you what evidence I do think is there, however.
Q. Now, we've talked about different types of talc that might have different constituent components, but you also look at exposure to talc in an occupational setting.
Do you recall that?
A. Some of the studies that I've relied upon, yes, some of them were occupational.

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Q. Okay. And you understand that in an occupational setting, you would agree that the exposure, particularly via inhalation, would be much higher than it would be through the use of a consumer product, correct?
A. It depends on the occupation, but, yes. For example, I would agree a miner would be expected to have that, but there are certain, quote/unquote, occupational studies where the exposure levels that -- for example, there are -- I believe there's at least one study that looked at application of talc powders in -- maybe in a material, coating materials in a factory. Those kinds of studies would be different than a mining study.
But, certainly, yes, I understand that occupational studies, the inhalation exposure is the pathway that would be predominant versus in the consumer body powder use, I'm talking about the predominant exposure pathway in my opinion is going to be through perineal use, even though inhalation exposure can occur.

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Q. Is it your opinion as you sit here today that someone could develop ovarian cancer through -- exclusively through the inhalation of Johnson's baby powder?
MS. PARFITT: Objection.
THE WITNESS: I haven't formed that opinion at this point in time.
QUESTIONS BY MS. BRANSCOME:
Q. Have you done any analysis or can you point me to any analysis in your report that makes a comparison of the exposure levels that might be seen in an occupational setting to what would be seen by a consumer?
A. Are you asking me for a piece of evidence that does that comparison, or is there evidence that allows you to do that comparison?
Q. Have you cited or discussed any of the evidence or done an analysis in any way that would compare exposure levels in an occupational setting to what you would anticipate a consumer using Johnson's baby powder might be exposed to?
A. I don't think I did it as a

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separate analysis, but as part of my analysis I considered evidence that showed -- provided me with such data. So, for example, if you want, I can point you to a -- I have an inhalation paragraph, I think.
Let me look for it real quick. See if I can find it quickly for you. I don't want to waste your time.
Q. Sure.
A. So there's -- I don't see it cited here, but there's at least one document I reviewed where the company themselves made a comparison, and I have seen that, of inhalation exposure to talc suspended in air with diapering. Dr. Longo has done a measurement of exposure in air with perineal application of talc. So I'm aware of those studies.
And then I certainly am aware of the fact that those numbers are different, or smaller, than many of the numbers I see reported in some of the occupational studies. But I can't say that's true for all.
I would certainly, though, say that if you're just talking inhalation, I

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certainly would expect a miner or a miller to have a greater potential for inhalation exposure than routine use of the consumer product, with the exception of the studies -- the reports of large amounts of exposure in children where the inhalation -- where they were inhaling large amounts of powder.

And so that's a different story. That's sort of an acute overdose exposure, I guess, versus the typical daily exposure through occupational or consumer use.

Q. And that raises an interesting question. You discuss health hazards associated with talc being known, and in some cases deaths had been reported.

You're aware that those relate to asphyxiation deaths, correct?

A. Or long-term injury to lungs. Maybe not an immediate asphyxiation, but lung damage produced by large amounts -- some of the children would go to the hospital and be sick for a while and then die. So they didn't asphyxiate immediately, right? But some of them did. You're exactly right.

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Both of those things occur, and I address that also in my warning section about the fact that that warning didn't -- was not put on the product for a long period of time even though those types of reports were coming in early.

Q. You would agree that that is a completely different biologic mechanism than what you are proposing the biological mechanism is for ovarian cancer to develop with respect to talc use, correct?

MR. MEADOWS: Objection.

THE WITNESS: I would agree that it's an acute response versus chronic, yes, that I agree with.

It's not entirely different in some cases because some of the tissue reactions you saw were indicative of irritation when some of the lung samples were looked at. But certainly, yes, that's acute exposure versus chronic exposure, and I'm focusing on ovarian cancer on chronic exposure scenarios.

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QUESTIONS BY MS. BRANSCOME:

Q. Okay. Now, you would agree that -- so let's set aside inhalation.

You agree that for talc -- for Johnson's baby powder or another one of Johnson & Johnson's consumer talc products to reach an individual's ovaries, it must pass from the perineum, through the vagina and the cervical canal, move across the uterus -- and again, it's the ciliary motion of the fallopian tubes -- cross the peritoneal space between the fimbriae and ovaries, escape phagocytosis in the peritoneal space, and then attach to the surface of the ovaries, correct?

MS. PARFITT: Objection. Form.

MR. MEADOWS: Okay.

THE WITNESS: If the issue is attaching to the surface, yes. There's also some information indicates the site of attack may be actually at the fallopian tube exit to the peritoneum. But, yes, that's correct, there's been some discussion in the literature on ovarian cancer

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about whether the tumors are arising in the tubes versus the ovaries.

But I would agree, I think both -- I think both of those things -- those things -- there is a passage that has to happen, regardless of whether the end point is at the fallopian tube or at the ovary.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. Is it your view that the consensus has been reached that ovarian cancer can be caused by talc landing in the fallopian tubes?

A. I haven't formed that opinion, though I do believe this will be discussed by some of the other experts.

Q. Okay. Have you personally conducted any tests or experiments to confirm the theory that talc migrates from application at the perineum to the ovaries?

A. If by that you mean something where I performed a laboratory test myself, no, I have not done that.

Q. As a toxicologist, are you capable of doing that?

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A. Yes, I believe if asked I could -- I could attempt to design something to look at that issue.
Q. Okay.
A. But I would argue that I think it doesn't make a lot of sense to revisit based upon what we already know from the scientific literature and the review papers from the gynecological community. I believe it's -- it's understood that it can migrate.
Q. In your opinion, has an animal model been successfully developed that would allow the testing of talc migration in humans from the perineum to the ovaries?
A. I think I tell that you in my report. I believe that the human data is the relevant data to look at this issue.
So it would be very difficult to design a study to do this based on the typical laboratory species that are used in toxicology testing. Even -- even the monkeys have issues, and the biggest issues with monkeys is the ethicality of using a monkey to settle -- to address a question that I believe is settled within the gynecological

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and scientific community.
Q. Now, you state in your report that talc that's applied through perineal use -- I believe the term you use -- routinely migrates to the ovaries.
Is that your opinion?
A. Are you reading from my report?
MR. MEADOWS: To the extent that question is still lingering, I object to it.
QUESTIONS BY MS. BRANSCOME:
Q. On paragraph 43 on page 29.
A. So I think as I've stated it, the studies that I have reviewed demonstrate that inert particles routinely move from the lower female reproductive tract up into fallopian tubes and towards the ovaries.
Q. What do you mean by routinely?
A. It's the percentages of movement that are reported in the patients. In other words, if you look at some of the individual studies -- if you want we can pull them out, but, you know, eight of ten patients, nine of ten patients, all the patients showed movement of the particles.

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And then on top of that, you have the review articles that talk about migration of particles in the female reproductive tract and are describing it as an event that is known to occur. So it's those things weighed together.
But certainly routine could be supported by the observations where the majority of the patients in the studies were showing movement of inert particles.
Q. Is it your opinion that every perineal application of cosmetic talc powder results in talc being deposited on the ovaries?
A. I have not formed that opinion, no.
Q. Have you formed an opinion as to with what frequency -- so let's say someone uses a cosmetic talc on a perineal application ten times. Out of those ten times, have you formed an opinion as to how many of those instances would talc deposit on the ovaries?
MS. PARFITT: Objection.
THE WITNESS: I haven't formed

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an opinion in that particular way, no. I think what I've -- I've tried to describe to you in my report is that I believe it is known that inert particles have the ability to migrate. And based on that, I form the opinion that it's my opinion to a reasonable degree of scientific certainty, which would be a more likely than not standard, that particles of talc would be migrating when women are using them perineally. But I haven't told you that it has to be a specific number, no.
QUESTIONS BY MS. BRANSCOME:
Q. Have you done any analysis to establish over a lifetime use of cosmetic talc where the app -- the perineal application, with what frequency during a lifetime the talc may have been deposited on that individual's ovaries?
A. So I certainly looked for information to allow me to assess that, but unfortunately those kinds of studies would be unethical to do. Because that would be a

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matter of sampling women during -- using them and then taking biopsies, and that's something that would be difficult to do. I would say impossible to get approval to do under human testing guidelines.

Q. Okay. So it's your opinion that it is possible for talc that is applied through a perineal application to reach the ovaries, but you cannot say with what frequency that occurs?

MS. PARFITT: Objection. Form. Misstates her testimony.

THE WITNESS: That's not -- what I'm telling you is, I think it -- that to a reasonable degree of scientific certainty that it migrates, and that would be the standard of more likely than not. I think it's more likely than not that the talc is reaching the ovaries when people are using it perineally.

I did form the opinion -- and I've talked about this at trial and yesterday. I have formed the opinion that this is a issue of chronic or --

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or use of the products. In other words, people aren't just using it once, but people are using it -- you can use the word "routinely," as a habit, in their daily life perineally. And that would be consistent with the studies that have been done that have looked at the issue of dose response.

And I discuss that in my report, too.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. But you have not made an attempt to quantify, nor have you seen it in the literature, the overall dose of talc that someone might be exposed to in terms of contact with the ovaries throughout their lifetime, chronic use of cosmetic talc?

MS. PARFITT: Objection. Form.

THE WITNESS: Those -- that's the kinds of studies that have not been done and I believe could not be done based upon ethics of human testing. But certainly I -- that -- that data is not available that I'm aware of.

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MS. BRANSCOME: Okay. Can we just go off the record for a second?

VIDEOGRAPHER: We are going off the record at 12:23 p.m.

(Off the record at 12:23 p.m.)

VIDEOGRAPHER: We are back on the record at 12:24 p.m.

QUESTIONS BY MS. BRANSCOME:

Q. As you sit here today, how would you characterize the biological mechanism by which you claim Johnson's baby powder, their other cosmetic talc products, present a risk of ovarian cancer?

A. So I outline this for you in the MDL report. I think I have a section on -- let's see if I can -- you want me to tell you where or...

So paragraph 65, I think I set out part of this argument or part of this. And then also in paragraph -- I believe in 67.

Q. All right. Well, let me take a step back.

Is it your opinion that the biological mechanism by which talc, cosmetic

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talc, can in your view cause ovarian cancer, is that something that has been definitively established?

A. What do you mean by definitively? I mean, I think -- I believe more likely than not that -- so I believe I have reached a conclusion that I think what the most likely biologically plausible mechanism, but maybe you're ask -- meaning something else.

Q. Okay. Well, let's start with specifically you discuss a number of different potential mechanisms in your report. So if you believe you have reached an opinion more likely than not about the specific biological mechanism by which cosmetic talc and specifically Johnson & Johnson's products can cause ovarian cancer, can you describe that for me?

A. So it's a chronic inflammatory process, and so -- but like all compounds, constituents, even drugs that we look at, we don't know each individual step within the molecular mechanism.

Instead, what we know is that

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there are certain components to the process of cancer that are consistent with the effects produced by talc, and we know that talc can produce a chronic inflammatory process.

And so that's why I was pointing you to the paragraph 65 and I think 67.

Q. Is it your opinion that consensus has been reached in the scientific community that cosmetic talc can cause ovarian cancer through a chronic inflammatory response?

MS. PARFITT: Objection.

THE WITNESS: I don't know that that's exactly the opinion I've formed.

Would you like me to -- I could restate what I believe, but I don't think that's exactly how I would state it, no.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. So then yes or no: Has consensus been reached in the scientific community that cosmetic talc can cause

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ovarian cancer through a chronic inflammatory process?

A. I don't believe I formed the opinion either way, that it's yes or no, because I haven't tried to -- I haven't tried to form the opinion about what the -- in other words, I haven't -- I can't say for every scientist out there.

I certainly can tell you what I believe based on what the consensus of science says about mechanisms underlying cancer and the consistency of those mechanisms with talc, and then I have an opinion about what I believe that information says.

I do believe my opinions, however, are consistent with some consensus statements, such as the issue on the mechanism is consistent with consensus opinion reached by IARC, where they discuss the inflammatory process as an underlying biologically plausible mechanism that can lead to ovarian cancer.

I think it's consistent with the Canadian risk assessment where they

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discuss those issues.

I think it's consistent with -- I don't know if the ACOG statement goes that far on mechanism, but it does talk about ovarian cancer. That's a recent statement.

And I believe it's consistent with some of the -- I believe my opinions are consistent with some of the opinions reached by others in science, but that's the only way I can answer that for you.

Q. Okay. Because you have not, one way or the other, done an evaluation of whether or not chronic inflammatory process is a biological mechanism on which the scientific community has reached general consensus with respect to the causation of ovarian cancer; is that correct?

MR. MEADOWS: Objection.

THE WITNESS: I can't tell you that -- I can't tell you that every body that's looked at it, but I have tried to point you to evidence that I believe is consistent with that.

For example, the IARC would be a good example of consensus on

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biologic mechanism because they have a whole part of their assessment of non-asbestiform talc and perineal cancer -- of perineal use and ovarian cancer that discusses mechanism. And that is consistent with what I have said. So there is a consensus opinion.

But I guess what I'm saying to you is I can't tell you that all -- all people who have put statements have come to that exact opinion. But there aren't that many places out there that are addressing that issue as far as the consensus on a mechanism. There's more statements about the relationship between ovarian cancer and talc use than there are drilling down to what the mechanism must be.

QUESTIONS BY MS. BRANSCOME:

Q. Okay.

A. So that's the issue. It's a little -- it's a little hard to answer that yes or no because of that.

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Q. Okay. When we talk about the idea of biologic -- a biologically plausible mechanism, what is your understanding of the term "plausible" in that expression?
A. When I use the word "biologically plausible mechanism" or "biologic plausibility," I'm using it consistent with what Bradford Hill uses, that's it's the idea that the evidence that available makes -- the evidence that available supports a pathway where you can go to exposure to response.
So in other words, there's a -- the biological information is consistent with how we know cancer can develop. That's the response we're looking at. And the exposure we're looking at is known to produce those kind of biologic events.
So as a result, based upon knowing that there's a consistency between the data that we have on the -- on the exposure and the data that we have on the way cancer can occur, those things -- those things align. So that makes it biologically plausible that that could occur.

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Q. But you would agree that biological plausibility suggests that it is a plausible explanation, but it may not have been established as the definitive pathway by which a disease is caused, correct?
MS. PARFITT: Objection. Form.
THE WITNESS: Well, I would agree that in the discussion of biologic plausibility in the Bradford Hill paper that is true. But if you look at people's discussion of the use of -- I want to say "biological mechanism" rather than the word "biologic plausibility," because really as a toxicologist I'm trying to understand whether there's a biologic mechanism that makes sense. Those are words I like to use. Does it make sense that this exposure could lead to this response.
And that involved looking at the mechanistic data or the data on the way toxic responses are produced by talc, and whether or not they align with the types of toxic insults that

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are known to be able to produce, specifically, ovarian cancer.
QUESTIONS BY MS. BRANSCOME:
Q. Is it your opinion that IARC, for example, has concluded that the biological mechanism by which talc may cause ovarian cancer is chronic inflammation?
MS. PARFITT: Objection.
THE WITNESS: I don't know that they have used -- they've described it quite that way, but they do describe what they believe is the biologically plausible mechanism. Because they do organize and use within the definitions of how they describe some things that are consistent with what Bradford Hill uses.
QUESTIONS BY MS. BRANSCOME:
Q. Okay. And obviously you're familiar with the IARC evaluation of talc with respect to the possibility of causing ovarian cancer, correct?
A. Yeah. If you mean the recent one, yes, the most recent assessment.
Q. Yes.

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And that IARC has in fact classified cosmetic talc not containing asbestos as possibly carcinogenic to humans, correct?
A. It's a possible human carcinogen 2B, that's correct.
Q. Okay. And if a product is listed in the 2B category, does that necessarily mean the product, in your view, is carcinogenic?
A. Not always, because that comes down to an assessment of -- then you're putting together a -- a risk assessment that looks at -- looks at -- across the information that you have available. And that may be that -- that the -- the possible is all you can say, or it may be that you believe that the information -- there's enough information there to take it further.
Has a possibility -- that's what I said, they do a hazard assessment. They rank things on hazard based on -- on unlikely -- not enough evidence, less -- the possibility, the probability or it's known.
Q. In your opinion, is your

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characterization of the risk of Johnson's baby powder or talcum powder products with respect to ovarian cancer, are you in the MDL characterizing that risk as a higher level of risk than what IARC characterized it, or do you agree with the 2B characterization of possibly carcinogenic?

MS. PARFITT: Objection. Form.

THE WITNESS: So I'm not IARC, so I don't try to second-guess there. They have reached a conclusion, and I use that as part of my weight of the evidence. So I haven't formed the opinion they're right or wrong.

But I have done a different assessment. My assessment, first off, includes more information than IARC had, so as a result, I have formed the conclusion that I believe that it's more likely than not that exposure to -- perineal exposure to talc body powders increases the risk of ovarian cancer in women who use that product.

And I will put the caveat this has to be chronic use or repeated use,

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because I've gone -- I've said that many times.

So that -- that is my opinion. So that's a different statement and a different assessment than what IARC does.

But -- so I don't disagree with their possible -- I weigh that, but I believe the evidence for the risk assessment shows me that it's more likely than not that this -- this exposure will increase the risk above a background risk for women who are using this product.

QUESTIONS BY MS. BRANSCOME:

Q. And how do you define chronic or repeated use?

A. Well, that is variable within the literature. For me, chronic is exposure -- if as a toxicologist, I would typically say chronic use is years of use. It doesn't have to be daily, but it would be years. That's the most common description you see in toxicology, so I would say that's fair. That's a fair assessment of my

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opinion.

Q. Is there a threshold of the use of Johnson & Johnson's talcum powder products below which there is no increased risk, in your opinion, of ovarian cancer?

A. We have not identified that threshold. That's what's missing within the -- the literature that exists today. So I can't tell you whether or not with only a thousand applications over a lifetime that is -- is not enough for every individual or not, but certainly I do believe that the -- that the exposure has to be habit, routine, chronic, something that is done maybe not on a daily basis but on a routine basis in a woman's life.

So that is consistent, I think, with the literature.

MS. BRANSCOME: Okay. We can go off the record.

VIDEOGRAPHER: We are going off the record at 12:36 p.m.

(Off the record at 12:36 p.m.)

VIDEOGRAPHER: We are back on the record at 1:35 p.m.

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QUESTIONS BY MS. BRANSCOME:

Q. Good afternoon again, Dr. Plunkett.

A. Good afternoon.

Q. I want to talk a little bit about the Health Canada assessment.

We talked about this before, but this is something that you reviewed after you completed your report which has been marked as Exhibit 4, correct?

A. Yes, and I wanted to tell you, I did not bring all those documents printed. I apologize. So there is a separate Health Canada draft risk assessment that I didn't print.

Q. Okay. So when you're referring to the Health Canada analysis, what document are you specifically referring to?

A. So I'm referring to the -- the combined documents, but there are times when you've asked me questions that I've been referring -- and I tried to say, I believe, Taher.

But, yes, some of the questions you asked me when I said Health Canada, I was

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talking about the combined documents, which would include their -- I guess it's called a draft risk assessment document, yeah, which refers to this document but is a separate -- is their own separate statement.

Q. As you sit here today, what is your understanding of the current position that has been articulated in the collection of documents that you refer to as Health Canada with respect to any potential relationship between cosmetic talc and ovarian cancer?

A. So that's why I did print out the small one, because I think it summarized it. So here, if you look at this Exhibit 6, it makes specific conclusions or draws -- makes statements. And essentially it talks about talc being a possible risk of ovarian cancer, but then it gives women specific advice about what to do in order to minimize exposure to the products, and some of that was relevant as well.

Just one reason I printed it out, it has to do with either choosing an alternative product or avoiding genital

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exposure to talc.

And let me see the exact words that they use, but --

Q. Before you do that, do you agree with the characterization that cosmetic talc presents a possible risk of ovarian cancer?

A. No, I don't think that's my opinion. I think my opinion is stronger than that.

But are you talking about my causation analysis opinion or just my risk assessment opinion?

Q. I'm asking about any opinion you intend to offer in the MDL.

A. Okay. So I will not be giving the causation analysis opinion, so that -- I will take that off the table.

So I think my opinion is a little stronger because I say that the exposure to the perineal -- the talc by perineal application in women increases the risk. So I'm not saying it's a possible risk. I'm actually -- I believe that it increases the risk. And I do believe that

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there is a association between those two things, the exposure and the response, which is more than a possible association, if you want to use those words.

But my assessment that I've done is not exactly the same, for example, as IARC does, which is more of just a hazard assessment.

Q. Right.

So I'm focusing my questions now on your risk assessment as compared to the documents that you've supplied us with with respect to Health Canada. And if I understand it correctly, are you stating that your opinion with respect to the relationship between cosmetic talc and ovarian cancer, you believe that it is an association that is stronger than a possible risk; is that correct?

A. Well, I don't say it's a possible risk; I say there is an increased risk. So I think it's a different statement, yes, absolutely.

Of course, I'm not Health Canada, so, you know, they have a framework

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upon which they make decisions, and I'm doing an analysis based on what I have done. And so it's not exactly the same, although some of the same documents and information is weighed within -- and then that's when you have the issue of what Health Canada does versus what they rely upon.

But this Taher risk assessment is just one piece of information that Health Canada has weighed in their assessment if you read their -- their draft risk assessment.

Q. So the question I have about the Taher risk assessment, earlier you were referring to the fact that you have only seen a quantitative assessment of the weight of particular components of scientific evidence in evaluating epidemiological studies; is that correct?

A. So that's what I typically see, yes. And I don't know that -- I've never seen it. But the typical approach would be to use it there as opposed to using it in the context of a human health risk assessment based on animal in vitro data.

Q. All right. Are you familiar

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with something called the Klimisch scoring system?
A. I don't know if I am now. You'll need to show me what it is you're referring to. The name doesn't ring a bell, no.
Q. Okay. So it's not something that you've used in the past?
A. No, not that I recall using.
Q. All right.
A. Unless it has another name, and that's why I'm asking you.
Q. All right. So if you have actually -- it's the document in front of you that we've already marked as Deposition Exhibit 5, I believe.
A. Yes.
Q. And that is the Taher study that we were discussing and is cited by the Health Canada risk assessment.
If you turn to page 5 -- well, actually beginning on page 4, do you see there is a section entitled "Literature Search and Identification of Relevant Nonhuman Studies"?

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Do you see that?
A. Yes.
Q. And this is related to an analysis that these authors performed on potentially relevant animal and in vitro studies, correct?
A. Yes, that is true.
Q. All right. And it states here that "all retrieved studies were examined for relevance, reliability and overall quality using the Klimisch scoring system."
Do you see that?
A. Yes, I do see that. So I have seen that before. I just didn't -- I didn't recall it.
Q. Okay. And so would you agree that it is possible and in fact has been done in a study that you rely on to apply a quantitative scoring system to animal and in vitro studies, particularly in the context of looking at the relationship between talc and ovarian cancer?
A. Well, I didn't say it was impossible. I said I don't believe it's routine based on my experience.

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So, yes, if they stated they've done -- we'd have to pull the supplementary materials out, but I recall them doing scoring based on epi studies but not on the -- all of the animal studies that they talk about. But we can pull it out and look. I could be wrong.
Q. Okay. Did you review the supplementary material 7, 8 and 9?
A. Yes, I did, and we'd have to pull them out because I don't recall the details.
Q. All right. We may take a look at those in a minute.
It talks about them classifying the animal and in vitro studies into four categories of reliability.
Do you see that?
A. Yes.
Q. So did you make any attempt, when you were reviewing the various studies in reaching your opinion about the potential risk of talc in causing ovarian cancer, did you make any attempt to separate out the different pieces of evidence into categories

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of reliability like the authors of this paper have done?
A. I didn't do it exactly the way they did it, but I certainly do do that as part of my screening.
I told you one of the characteristics or one of the assessments I make is whether I believe the data is reliable data that I can -- that I can use in a weight of the evidence. So I make a -- and when I talk about reliability, I'm talking then about things such as I mentioned, peer review, whether or not there is statistical analysis, whether or not the study is designed in a way that's consistent with general principles of toxicology, control groups or not control groups.
Those kinds of things I do -- I do consider when I am assessing the use of a study or not.
Q. Is it your testimony here today that contained within your report that's marked as Exhibit 4, I could find categorization of reliability of each of the pieces of scientific literature that you have

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included in your weight of the evidence analysis? Is that your testimony today?
A. No, that's not what I'm telling you, no.
Q. Okay. So you would agree that you did not -- first of all, did you develop categories of reliability in which you separated the particular scientific studies into as part of your weight of the evidence analysis?
A. I do look at -- I do categorize studies based upon my assessment of their reliability and their ability to be used to answer the question I'm asking, but I -- I already told you, I didn't do it the way it's set out here. I didn't have these specific five categories, no. That's not what I did.
Q. Okay. Other than the CIR 2013 publication, which you have said that you do not find reliable and you assign little weight to it, can you point me to another place in Exhibit 4 where you assign a specific category of weight that you have given to a particular study that you include in your weight of the evidence analysis?

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A. If what you're asking me is do I make a specific statement next to each study that I discuss about little weight or great weight, no, I don't do that, if that's what you're asking me.
Q. Okay. As part of the collection of documents that relate to Health Canada that was provided to us as part of your new reliance list, did you review a document entitled weight of the evidence -- or "Weight of evidence: General principles and current applications of Health Canada"?
A. Yes, I've seen that.
(Plunkett Exhibit 8 marked for identification.)
QUESTIONS BY MS. BRANSCOME:
Q. All right. We will mark this as Plunkett Deposition Exhibit Number 8.
All right. The document that I just handed you that's marked as Plunkett Deposition Exhibit Number 8, are you familiar with that document, Dr. Plunkett?
A. Yep, I've seen this before.
Q. Is this listed among the new materials that have been added to your

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reliance list?
A. I believe it was, yes.
Q. Okay. And so for this one I just want to direct your attention to the conclusion section -- well, let me ask you first: How does this document relate to the collection of documents with respect to Health Canada that you identified as relevant to your opinion?
A. It was one of the materials that they rely upon or they cite. That's the reason I pulled it. It was -- I pulled documents that they provided on the website that were cited.
Q. Okay. And if you could turn to page 11 of that document, there's a conclusion section. The first sentence of the third paragraph reads, "The given -- given the context-specific nature of each risk assessment and the diversity of tools and criteria applicable, transparent documentation of the specific application of the WOE approach is especially important."
Did I read that correctly?
A. Yes, you did.

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Q. And is your understanding of WOE that it is weight of evidence?
A. Yes, that's correct.
Q. Do you agree with this statement?
A. In a regulatory context, I do believe that that is true, because within the regulatory context when they do the risk assessment, there's a need to understand why decisions are made. So, absolutely, in a regulatory context, I would agree that this kind of transparency is even being adopted by EPA.
Q. And is it your opinion then that a different level of transparency is needed for expert testimony in court?
A. No, that's not what I'm saying. I'm saying that's a different process. And that's what part of this process is. It's understanding the ability to provide a dialog about what was done.
So as a result, this is something that is common to the work that I've done in the past. Even in a nonlitigation context with my regulatory

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clients, doing a risk assessment doesn't necessarily involve the same level of detail that a regulatory -- a regulator would apply to the transparency of the assessment. Not to say that it couldn't be done, but it's just -- I would say it's not necessarily typical.

Q. So this specifically refers to transparent documentation.

Do you see that?

A. Yes.

Q. Would you agree that the report that you have produced in the MDL does not have documentation of the specific application of the weight of evidence approach?

MS. PARFITT: Objection. Excuse me, objection. Form.

THE WITNESS: I disagree to an extent because I did attempt to provide in my report a description of the methods that I used and the resources that I've relied upon for a discussion of how those methods are used.

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And then in addition to that, I've attempted to lay out for you in my report a discussion of the pieces of evidence that I've relied upon, including some -- for some of those -- that's one of the reasons I got so detailed in the section on migration and providing you an analysis of each of the papers that I relied upon and what I thought was important within them that led to my -- the formation of my opinions.

So I disagree to some extent.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. Turning back to what Taher did in classifying different studies into different categories of reliability. Have you done that type of analysis in the past where you have separated out different studies into different categories of weight or reliability as part of an overall analysis?

A. Well, I do that every time I do a weight of the evidence when I separate into categories first based upon the type of

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study. In other words, as I discussed many times in deposition, when you're talking about doing a human health risk assessment, there's certain types of data that are most relevant. I mean, when they use the word "reliable" -- I don't know that many of these studies have the same level of reliability as far as peer review, but they're -- for example, on the issue of migration, it's my opinion that the data from the human studies is a more reliable or relevant source of information. And I've laid out why, because of differences in the anatomy, things like that, with the data.

Q. Are you familiar with the term "binning exercise"?

A. Yes, I am. And that is certainly something that I have used in other aspects of work that I have done.

Q. Did you do a binning exercise in rendering your opinions and what you've provided to us in the context of your opinions in the MDL?

A. Yes, that's the exercise I start with. I'm binning them into human,

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animal, mechanistic, in vitro data. That's the first bins.

In fact, in the copper work we did, that's what we did. We separated the data into in vitro/only mechanistic information, animal studies, did we have human studies.

And we also looked at studies -- we had a separate bin of exposures like I do. I have studies that just address the issue of exposure potentially.

So, yes, it's -- it's consistent with doing that. It's -- essentially binning is just separating the information into groups based on what questions those -- those data can answer.

Q. Okay. Have you ever -- do you ever separate them into bins based on the level of weight that you would give a particular study?

A. I do that when I'm analyzing each of the studies within that group or that bin. That's what I do. I give them -- in my weight -- in my analysis, I weigh those studies based upon my judgment on the

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relevance, the reliability, the power of the study, the statistical analysis that's done, the inclusion in animal studies, in particular, of controls. Those are all parts of that analysis that I do. So, yes, I do do that.

And then in -- there have been exercises that I've done in the past with other individuals where we may have taken a yellow sticky note and put down on top of it animal data with exposure information, animal data without exposure information. That's the process that I'm doing when I am looking across the data. I'm separating those pieces of data into groups and what types of questions they can answer.

So that is consistent with what I do when I do a weight of analysis approach in the work that I do in both nonlitigation and litigation context.

Q. Okay. But we have no specific documentation of the different ratings that you gave the various pieces of evidence that you included in your weight of the evidence analysis, aside from occasional references to

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giving something less or more weight, correct?

A. Well, I certainly -- I told you I have not given numerical values that you're asking me, but I've attempted to do that when I have described them in groups, when I talk about human versus animal versus in vitro. Because I've already told you, I believe, it's my opinion that certain types of information are more informative than others. And so the more informative it is, the more weight you're giving it in -- obviously in your analysis.

But it is a different exercise than what is described here. And here I'm pointing to Exhibit 8. And it's a different exercise, obviously, than what a regulatory body is required to do where they are trying to come up with ways to increase the transparency when no one can go and actually talk to each of the regulators individually to understand what their thinking was.

Q. Okay. Returning to biological mechanism for a minute, why doesn't inflammation generally, including chronic

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inflammation, cause ovarian cancer?

A. Because it doesn't change the phenotype of the cell. It has to -- the -- and I discuss that. You have to -- you have to set up a chronic inflammatory process that leads to changes within the cellular phenotype to go from a cell that is -- that is -- is dividing normally to a cell that isn't.

So it's -- it's the same issue that you address even in a study in animals. Why do not all animals exposed to -- exposed to a chemical develop tumors. It's the idea that something has to be initiated beyond the exposure or maybe beyond inflammation to lead to the series of events.

And so, yes, it's recognized that you can get inflammation, and inflammation can go down the road in becoming a carcinogenic process, or inflammation can no longer -- can stay where it is. It doesn't progress beyond just a chronic inflammatory process.

Q. And so if you had a study that demonstrated that a particular agent causes

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inflammation, you would need more information in order to make the conclusion that that agent can in fact cause cancer, correct?

MR. MEADOWS: Objection.

THE WITNESS: You would look for more informative information, exactly, which is why, when I've talked about the individual constituents in the context of consistency on mechanism for cancer, I've pointed to documents where that information has been discussed.

So like when I talk about asbestos or cobalt or I point to the -- for example, the IARC assessment where they go through that -- that discussion of the fact that there's not just data showing that a biologically plausible mechanism may be inflammation, but there's also data to show that that can lead to tumor development as well.

QUESTIONS BY MS. BRANSCOME:

Q. Okay. How does talc change the phenotype of the ovarian cell?

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A. So this is one of the details we don't know, other than generally it's changing the phenotype to go from a normal cell to a tumor cell. That is being observed. When you find the presence of the tumor, that is what you're observing.
Q. Does pure talc with no other constituent components, can it change the phenotype of an ovarian cell?
MR. MEADOWS: Objection.
THE WITNESS: So that's a difficult question to answer with certainty because of the fact that I don't believe that we have assurance that any of the studies are done with essentially pure talc.
However, in the studies that claim to have been done with pure talc -- for example, the NTP study claims to have been done with pure talc. So if that is pure talc, truly is, then that study is an example of evidence for the chronic inflammatory process leading to preneoplastic lesions that are setting down the road

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mechanism towards cancer.
So there are data out there. The problem you have, I believe, in the literature is whether or not, based on the discussion that is becoming apparent now with sensitivity and ability to take the natural product and actually determine exactly what's in it, that I don't think there is the ability to assure that any -- any of these studies with the samples of talc they're using is absolutely, 100 percent, only platy talc. I think there's -- there's some concern about that. But certainly you will take -- you have to take what is discussed within the study as evidence from what they're claiming.
So many of the studies say we used asbestos-free talc or platy -- pure platy talc and we got a toxic response.
QUESTIONS BY MS. BRANSCOME:
Q. Would it be possible to design an experiment -- and now I'm talking about an

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in vitro or an animal experiment -- by which you would expose either cells or animal to talc with different constituent products to identify or separate out the individual effects of the components? Is that a study that you could design as a toxicologist?
A. I think that would be difficult to do, but I'm not saying impossible to do. And here's the -- there are some very specific considerations you'd have to put into that design.
I would argue that some of that is already available, where we have studies that have looked at the dose-response effects for toxicity with cobalt, with chromium, with asbestos.
When you get to asbestos and talc, it's more problematic because then the question is what is -- what is it? What are the specific characteristics in all the different studies of exactly what the asbestos was versus exactly what the talc was.
But I think you could attempt to do that, and then the question would be,

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being able to use that data not so much to -- not so much to identify a dose response for a certain insult, but to look at the fact -- look at potency differences across the compounds. And then there's the issue of then looking at additivity when you know you have a complex mixture.
So that could be done, but, again, it would be difficult to do based on what we know about talc, being able to really know that -- you would have to really be very careful that what it is that you're looking at is -- is not containing any of those things that we unfortunately know co-occur with constituents within the natural product.
But no one has done those studies. I point that out. I haven't seen that study that you're asking for. I have not seen somebody do that.
Q. And a study like that would be relevant in evaluating the potency of the individual constituents and what might actually be the driving factor for phenotypic change, correct?
A. Not necessarily. I would argue

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that we already have an answer to that by looking at the data that's been collected on the complex mixture itself. So the issue would be why -- the question is what do you gain by being able to say that we're only pointing to this constituent or that constituent. That isn't what is occurring.

What people are exposed to is the complex mixture, not just each one of those individual components. To me this is not a case of asbestos-only exposure. This is a case of exposure to consumer products that are talc that may have within them at any given time -- and data indicates that there are substantial chance that asbestos may be in -- is in certain of these products.

But my opinions are not dependent on there being asbestos there at a particular level or copper there -- or, I'm sorry, cobalt there at a particular level because my opinions are based on the observations we have on the complex product as it exists.

Q. And you recognize that different types of talc and different talc

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products have different constituent components in different amounts, correct?

A. Some can. I agree with that. That is true.

So if you're being broad, as in pharmaceutical-grade versus industrial-grade or chemical-grade, yeah, because they'll have a purity level assigned.

But as far as what the -- what the components are, it isn't always defined even specifically within that.

Q. Okay. And does the presence of oxidative stress in a tissue indicate that cancer will develop in that tissue?

A. Will definitively develop? Not -- I don't think you could say definitively develop, but it's certainly in the biologically plausible mechanism that's been understood to lead to chronic inflammation and also has been linked to cancer.

So that's the issue of not necessarily saying it has to be there, but it certainly is something that is observed routinely in cases where carcinogenesis has

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been linked to an inflammatory response. Oxidative stress is often a triggering mechanism.

Q. Does the body have protective mechanisms that limit tissue damage from oxidative stress?

A. Yes, which is why not everybody that's exposed to any particular chemical is going to get cancer. Some people will respond better. Some cells will respond better. Some individuals in a population at one time in their life may respond better.

Q. You would agree that in vitro studies do not account for the body's natural defenses outside of what exists at the cellular level, correct?

A. Depends on the in vitro study that's being done and whether or not there is components added.

So I've seen studies done where they take cells and then add extra levels of glutathione to try to protect the cells from certain stressors that could lead to damage, but I agree with you that an isolated cell on its own is a different microenvironment than

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an intact tissue, which is a different environment than an intact animal, which is even different than an intact human being. Yes, they're all -- you look at those levels of evidence or those types of evidence differently, depending upon the end points you're collecting.

Q. And so you would give lower weight to an in vitro study as compared to an in vivo study, for example?

A. Depends on the question you're asking. I would give a lot of weight if the question is what do I know -- if I want to try to understand the biologically plausible mechanism, some of those in vitro studies are some of the most important, because it's the only ones that allow us to answer a question.

If the question is higher level about what is the evidence to show that there's an increased risk overall for cancer or a hazard for cancer, then certainly you need to have more than an in vitro study.

So as -- so on -- if you want to layer it up, obviously, if all you had was in vitro data, you'd have much less

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confidence in the conclusions you can draw unless you had some in vivo data. In vivo data is going to allow you to interpret the in vitro data.

So certainly there would be more weight given in that assessment to the fact that you had in vivo data.

Q. And so when you made the statement that, for instance, you always give more weight to human data, is that true, or does that also depend?

A. Well, it depends on whether you have human data. So if I have human data and I have a doubt, any doubts at all, about whether or not the exposure-response relationship would be affected by the way the animal studies are designed, then, yes, I would give more weight to the human studies.

In a case, however, such as inhalation exposure assessments where there -- it's much better, actually, to do an animal study where we can do a dose response across different sizes of particles and actually observe lesions as they develop over time, which is why I love -- I love the NTP

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93 study of interim sacrifices, looking at that issue. That data is very reliable in order to understand the risk of lung damage as compared to a human study where we don't have those serial time points, doses that are defined tightly.

So -- and the relevance between those kinds of initial lung injury in certain animals versus humans match fairly well.

That's my problem, though, in the case with the perineal exposure. I'm saying to you, because of the route of contact -- we need to be able to get it there to the tissue -- the human data is extremely important.

Q. So is it fair to say that in some circumstances animal data gets more weight than human data and in other circumstances human data gets more weight than animal data? It is circumstance dependent?

A. I would put it a different way. I would say in some cases animal data is weighted in a similar manner to human data. I don't necessarily say it would get more

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weight, but it could if you only had one crappy human study, one really badly designed human study, and I had a GLP quality cancer bioassay then, absolutely. I mean, IARC does this. They look at that animal data and say, "This one tells us -- answers the questions we want to answer, and this very poorly designed case series isn't going to allow us to do that."

So you could, but I would say it's more the other issue, that you look at animal and human more on an equal basis if the relevance and the extrapolation can be done reliably.

And that's the question you have to ask, can I extrapolate from animals to humans in a reliable manner.

Q. Okay. Would you agree that the response to cosmetic talc can vary depending on tissue type in the body?

A. Yes, I would say that that is true, whether or not there's certain protective barriers in place, for example, yes.

Q. And so in order to draw

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conclusions based on a study of one cell type's reaction to cosmetic talc to another, you would need to understand the differences in similarities between those two cell types, correct?

MS. PARFITT: Objection.

THE WITNESS: It's a different question. So you were asking me about -- I didn't think you were just asking about cells. I thought you were asking me about like routes of exposure, dermal versus inhalation. Those things differ.

Cell types may or may not. That may or may not be true. Because if two cells -- two different cell types in the body share similar characteristics as far as the -- for example, if they're both epithelial cells or mesothelial cells, those type of cells you would expect to respond the same way.

But I would agree that, for example, a neuronal cell versus a GI cell versus a liver cell, there could

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be differences in how they would respond, yes, and so you would -- you would look at those things individually.
QUESTIONS BY MS. BRANSCOME:
Q. And so it's important to understand the differences and the similarities between the different cell types before drawing conclusions using studies from different cell types?
MS. PARFITT: Objection.
MR. MEADOWS: Objection.
THE WITNESS: I certainly think you should consider the cell types that are being used and whether or not those cell types are ones that are relevant to your risk assessment question you're asking, yes.
QUESTIONS BY MS. BRANSCOME:
Q. Okay. You would agree as a toxicologist, dose is an important part of a toxicological analysis of an agent, correct?
A. If you're doing risk, yes. If you're only doing hazard, it may not be as important. It depends upon the question

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you're asking about hazard.
Do you want me to explain?
Q. I do want you to explain the difference between a risk analysis and a hazard analysis.
A. Okay. So in an initial hazard analysis, if the question is, is there a hazard associated with exposure, let's say, by inhalation, it may not matter whether it was a high dose or a low dose study. Both of those can identify hazard.
Then you ask the question: Is there a dose-response relationship? That's the next step beyond hazard.
So hazard is -- to me is identifying the end points that you're going to monitor for toxicity, sort of the target organs, those things, and so whether or not there's a dose-response study available, it wouldn't be as important.
But certainly when you go to that next step to assess risk, you'd like to be able to see whether or not there is a dose-response relationship in the effect that you're assessing.

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Q. Okay. And in your -- in your report, as part of your risk assessment that you did in the MDL -- this is paragraph 12 on page 8.
A. Yes, I'm there.
Q. Okay. You state about two-thirds of the way down the paragraph that "weight of the evidence methods were critical to defining the literature that identified the hazards of talc exposure as well as defining the dose-response relationship between talc exposure and the risk of adverse health effects."
Did I read that correctly?
A. You did. That's correct.
Q. All right. Is it your view that in the case you have reached an opinion that defines the dose-response relationship between talc exposure and the risk of ovarian cancer?
A. It depends what you mean by define. I can tell you what I mean in this sentence, and maybe that would help you.
Q. Dr. Plunkett, it is your report. And so I am asking you, using your

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own definition of "define," have you rendered an opinion that defines the dose-response relationship between talc exposure and the risk of ovarian cancer?
A. I have formed opinions about the dose-response relationship generally, but unfortunately -- I answered that question for you earlier when you asked me, I think, about is there -- I don't know if you used the word "threshold," but I did.
So the available information doesn't allow us to identify an ultimate threshold, for example, in the case of women exposed to talc perineally and their -- and their development of ovarian cancer.
Instead, in defining the dose response, what we can do with the data -- and that is what I attempted to do. This is where you look at defining the dose response in the animal studies, which we can look at, or defining dose response in cell studies, showing that as the dose increases, the hazard and the risk increase. So risk actually you quantify. There's a certain response at this dose and a different

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response at the next dose, or have we plateaued, that the responses are the same as dose increases.

So that, I did do that as part of my assessment, trying to define the dose as far as how that linked to the responses in each of the studies I looked at.

Q. You would agree, though, that some studies did not show a dose relationship between talc and ovarian cancer or the clinical signs that were indicative of the potential for development into ovarian cancer, correct?

MS. PARFITT: Objection.

THE WITNESS: If you're talking about the human data; is that what you're referring to? Or are you talking about all -- any of the data?

QUESTIONS BY MS. BRANSCOME:

Q. Any of the data.

A. So I would disagree on the animal data. I think on the animal data they often -- most of the animal studies I've relied upon have looked at more than one dose or at least looked a no exposure versus a

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dose, and most of them have looked at more than one dose.

In the case of the human studies, unfortunately, some of those studies were not designed to be able to define dose. In other words, the questions weren't asked, for example, of the individuals even in the prospective studies. Some of those included -- did not include the information collected on frequency and duration of use.

So if it's not collected, obviously, I don't have it to look at. And that's one of the limitations of human epidemiological investigations, is that it often is not designed appropriately to look at dose response.

Q. Is it your opinion that there are no studies looking at talc and the risk of ovarian cancer in which the authors of the study have concluded there was no clear pattern of increased risk with dose?

MS. PARFITT: Objection.

THE WITNESS: No, that's not what I've said. No. It's very possible that an individual paper

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or -- that they may make a -- an author may make a statement, but I'm talking about looking -- this is weight of the evidence. I'm looking across. And I'm saying, across the data, when I look at the human data versus the animal data, for example, versus in vitro studies, the in vitro studies and the animal studies allow you to look at dose response for talc toxicity.

The -- even the animal studies allow you to look at dose response for development of precancerous lesions, you're on the way to cancer, for example, in the NTP studies.

And then in the human studies, some of those studies are designed such that the authors could draw conclusions about dose response and some are not.

Even in some of the studies where they attempted to look at dose response, some of the authors indicate they don't see an effect. So that is

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true. And part of that may be driven by the design of the study, the number of individuals in the study, the way that the questions were asked. There's limitations on the way that information is collected.

If you want to look at each study, we can, but --

QUESTIONS BY MS. BRANSCOME:

Q. So my question to you, whether you agree or disagree with the author's conclusion, is simply that if you look at the overall animal and human studies that you cite in your report or have considered on your reliance list that look at a potential dose-response relationship for talc toxicity, do some of those studies conclude that there is not a dose-response relationship?

MS. PARFITT: Objection.

THE WITNESS: I disagree for talc toxicity, but I would say if you're going to limit it to the issue of the ovarian cancer response, I would agree. I have seen that in some of the studies.

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I think talc toxicity, I don't know if anybody has made the comment -- I would doubt it -- that there is no dose response for toxic effects of talc.
QUESTIONS BY MS. BRANSCOME:
Q. Okay. You discuss in your report -- wait a moment. It's in paragraph 58 on page 38. And I just want to make sure I understood what you were citing here.
In paragraph 58 you state that "It is important to remember that administration of even a single dose of talc in animals has been shown to produce adverse effects locally at the site of the exposure."
What are you referring to there?
A. Acute doses. In other words, in studies that have described installation of a single dose of talc in some form into a tissue, that they are observing adverse responses.
An example of that may be the -- I think it's Hamilton. Is that the

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one where they stilled it into the ovaries with a single dose?
Q. So these are large-dose exposures?
A. Well, not all --
Q. Or are they, I should say?
A. I don't know that they all are, no. There are -- there are -- I don't think I have attempted to quantify large in this sentence.
What I'm stating here is not an issue of large versus small. It's an issue of the fact that there are toxic effects with single exposures. And I'm just making the comment -- this has to do with hazard, right? It's the idea even a single dose -- or a single exposure you can get irritant, inflammatory reactions at the site of exposure. And that's all I'm trying to say. That's why I'm citing as reviewed by EPA. I believe EPA even makes a very similar statement.
Q. Okay. Do you take into account -- there are some studies for which -- at least my reading of your report

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is that you give them less weight because you believe that the individuals who conducted the study had been paid by either a company or agencies that had some investment in the outcome of the study; is that correct?
A. Is that my opinion?
Q. Yes.
A. For any particular study, you'll need to show me what you're pointing to. I do have opinions about some of the work by Drs. Huncharek and Muscat, yes. I think I address that specifically, and that has -- that's not so much to do with my weight of the evidence; that has more to do with transparency and what was being disseminated to the public and disseminated to the FDA as far as evaluations.
That's a different issue than the weight of -- the weight of -- the weight of the evidence assessment for risk. I think those were separate.
Q. So then I'll ask you that.
In doing your weight of the evidence analysis for risk, have you discounted the weight that you've given to

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any particular piece of scientific evidence based off of potential affiliations of the authors?
A. I certainly did with the CIR review document. I've already told you that. And that's because I have evidence that shows it's not just an affiliation issue, but it's actually -- it's more -- it's more important than that.
Q. Are there any other examples?
A. I think that's the only one right now as I sit here that I can tell you that I had identified as carrying little weight because of an issue of either authorship or input in the way it was described.
There are certainly studies within my weight of the evidence evaluation, some of which were performed by industry. I certainly look at that issue, but unless I have -- have a reason to believe that there's an inherent bias based on something I know, they go into the weight of the evidence without making a correction for that.
In many cases that I work in

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litigation, I will find situations like the situation here with Huncharek and Muscat where I have, for example -- I think this came up in the Risperdal litigation for me. It's the idea that there was a series of papers put out by an individual investigator where documents that I could get access to show me that indeed their analysis was not done by them but it was ghostwritten by somebody else. So that gives me pause, although I would never have known that unless I had access to internal documents.

So initial weight of the evidence I did not discount it, but then I went back and had to reevaluate the role those studies played in my overall assessment.

Q. Do you take into account in any way in evaluating the weight of a study if it is conducted by someone who serves as an expert on behalf of the plaintiffs in the active litigation?

A. It would be the same -- same issue. I certainly consider it as part of what I look at, but just like if they were an

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expert for the defense versus an expert for the plaintiff, you judge that information based on what you know. And if I don't have information to discount it, I will not discount it.

But absolutely, I understand. Just as people we all -- look at some of the things I've published where I have said my work was sponsored by the American Chemistry Council. You know, people -- that's why you disclose the conflicts. You put it there so people can weigh it if they want, but it doesn't mean you discount the work automatically.

And so I think for any paper, plaintiff, defense, whoever it is that's writing it, you need to consider it based on the information you have. And if you believe that you have information to indicate that there's some issue with the reliability of the analysis, then absolutely you consider that.

Q. So, for example, when you rely on Dr. Longo's characterization of the constituent components in samples that he has

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tested, that he reports are Johnson's baby powder, did you also consider the work that was done by experts that have been retained on behalf of the defendants to characterize the components of Johnson's baby powder? Do you give them equal weight?

A. So I haven't seen a variety of the documents that you're talking about, so -- because I have not worked in the litigation cases that have involved asbestos only. So -- which I think is where those documents are.

In the litigation I -- in the litigation I worked in, I am aware of what other experts on both sides have said. I don't believe I've seen an analysis from a defense expert that is -- that is like Dr. Longo's, at least in the litigation I've worked in. Certainly I would consider that and look at that if it's available, and I would consider it.

I would point out, Dr. Longo's analysis is not the piece of evidence that you start with, though. You start with what I discuss in the published literature first,

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because there are published documents out there in the literature that describe exactly what Dr. Longo is now describing.

Q. What published documents are those?

A. Those are Dr. Blount's reports in 1991, which is before the litigation came about, is my understanding.

There's also -- there's five or six. I can tell you the paragraph.

Q. For Johnson's baby powder, I would be interested in that, yes.

A. So I -- I'll have to look and see if it's Johnson's baby powder only, but certainly there is other evidence on the issue of asbestos contamination and specifically in talc.

So I -- you want me to find the paragraph for you?

Q. Please. If you think there is published literature documenting asbestos in Johnson's baby powder, I would like to see that.

A. So this is my paragraph 32. And I'd have to pull each of these articles

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out because I don't recall what each of them says. But I'm pointing to Paoletti, Blount, Mattenklott, Moon, Gordon, Anderson, Rohl, Pooley and Rowlands, Blejer and Arlon, Cralley, Millman.

And then I cite -- and then of course the next piece of evidence is there are actually documents from J&J and Imerys that show detection of asbestos or asbestos-like minerals in talc.

Q. As you sit here today, can you identify which of these published articles that you list in paragraph 32 relate to Johnson's baby powder?

A. I would have to pull them to answer that.

Q. Okay.

A. As I sit here, I'd have to pull them. But I would refer you -- I know at least some of them do based on the statement I've made, but...

Q. So you did not make an attempt in this paper to identify which products were being analyzed in these specific articles. It's not indicated on the face of this

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paragraph, correct?

A. I don't tell you on the face, but you if read the sentence I said, "When commercially available, talcum powder products were analyzed, including powders sold by Johnson & Johnson. The data has shown that the powders contained varied levels" -- and I'm saying "fibers," so it's just asbestos -- "including fibers that stated to be asbestos."

So to tell you which of those, I'd have to pull them. And I apologize, I didn't bring them all with me.

Q. Have you been provided -- you're aware that Dr. Blount's paper does not identify Johnson's baby powder in the face of the article, correct?

A. I believe that's true. You'd have to go to her deposition, I believe, where she's given -- where she discusses what the source of that was, and maybe even a -- there may even be a separate document, actually, not a deposition, that was -- that was in the files of Johnson & Johnson that goes along with that, but I'd have to go

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look.

Q. Have you reviewed Dr. Blount's deposition?

A. I have reviewed a -- something by Dr. Blount. Whether it was trial testimony or deposition, I have seen something, yes, that she has said regarding this issue.

Q. To the extent that there is confusion about whether or not a sample tested by Dr. Blount is in fact Johnson's baby powder, would you reduce the weight that you give that particular piece of evidence in evaluating whether asbestos has been present in Johnson's baby powder?

MS. PARFITT: Objection. Form.

MR. MEADOWS: Objection.

THE WITNESS: I don't know reduce the weight because -- because there's -- there are plenty of documents here that talk about that.

I would consider it -- certainly it would -- it's not so much weight. It's a different bin. We'll call it a bin, a different bin of

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information. There's information on talc powders generally, and then there's some information that's specific to certain body powders.

So certainly -- would I pay attention if they identified it? Yes.

But in the statement I'm making here, I'm not claiming that every one of these is relating to just the powder sold by Johnson & Johnson. This is across the available information that's public and then also the information that's available in the files of Johnson & Johnson.

QUESTIONS BY MS. BRANSCOME:

Q. What is your definition of asbestos?

A. My definition of asbestos is exactly what the different documents describe it typically. It's a fibrous mineral, typically. It occurs in a variety of different forms. Most of the times they'll say "asbestos." Sometimes they'll say "chrysotile." Sometimes they'll say "tremolite." Sometimes they'll say

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"anthophyllite." Those are the three most common ones I see. But those are all mineral forms of asbestos.

So just like IARC puts those all within one bin, I'm putting those all in one bin because they have a similar toxicity profile.

Q. Is it your view that each of the different types of asbestos has the same toxicity profile?

A. They all have the same ability to cause cancer, but they have different potencies. So they do have -- there will be some differences in the dose response and the potency of them, but certainly they've all been linked as being carcinogens by IARC.

And I would agree, when you look at their data, there is data and evidence to indicate that.

Q. Which type of asbestos is the most potent?

A. For which end point? For lung cancer? I believe chrysotile is. For other end points, I'd have to go look. I mean, chrysotile is the sharp -- is the sharp --

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the sharded-type structure.

But there's data on fibrous -- the fiber -- the fibrous forms of asbestos rather than the -- or the amphibole forms of asbestos as opposed to chrysotile, which is the serpentine form.

Q. Do you consider yourself an expert in asbestos?

A. Not in --

MS. PARFITT: Objection.

THE WITNESS: Not the geology of asbestos, no.

I have expertise in toxicology as it relates to interpretation of the data related to asbestos. I have never give -- given testimony in a case on asbestos, but it's something I've studied in the past in my work as a toxicologist, not as a testifying expert.

QUESTIONS BY MS. BRANSCOME:

Q. What role does your analysis of the possibility that there may be asbestos in Johnson's talcum powder products play in your risk assessment in the MDL?

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A. Has to do with the fact that we have a complex mixture that has multiple carcinogenic substances.

And asbestos is important from the aspect of the way that it has been assessed even by regulatory bodies, the idea that even very low levels of fibers pose a cancer hazard and a cancer risk in individuals have been shown to be carcinogenic.

So that's what I'm saying about potency of asbestos is different than potency of some other carcinogens that you might look at. But the importance of it is it's a complex mixture, talc, body powders, a complex mixture that includes constituents that are known human carcinogens as well as some that are -- been ranked other ways by regulatory bodies.

Q. If Johnson's talcum powder products do not contain asbestos, does that change your opinion with respect to the risk they pose with respect to ovarian cancer?

A. No, and I think that was very clear if you looked at my first report. So

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even -- there's -- I don't think in any of my reports I've opined that without looking at the complex mixture that we wouldn't be here.

In other words, I have not opined that if it doesn't have -- if it doesn't have asbestos, it's not a risk. I have not opined that, and I don't believe that, because I think there is independent risk for the fact that we have a complex mixture of talc that has been tested and shown to be carcinogenic.

It's my opinion, I told you -- maybe it wasn't you. I may have told this yesterday, I'm sorry, to Mr. Smith that I believe that there is evidence to show that there is a significant exposure to asbestos based on the data that's been collected.

But certainly, you know, in some -- the data has shown that in the assays that have been done or the analyses that have been done that you can't say that talc is asbestos-free.

Q. Well, so --

A. So --

Q. -- the question I have

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specifically relates to ovarian cancer.
Is it your view that through an exposure route that is relevant for ovarian cancer, that the use of Johnson's talcum products involve a substantial exposure to asbestos?
A. I believe based on the use of the products that -- where the data has been collected that there would be a substantial exposure to asbestos, regardless of how you're exposed, perineal -- perineally or by inhalation.
Q. What is your basis for reaching that conclusion?
A. It's looking at the number of fibers that have been detected in the products, in looking at the -- the widespread nature of the presence of asbestos fiber -- asbestos in the talcum powder products and the fact that even though it's at a very low level by their -- their level of detection, again, can't be said to be asbestos-free.
So regardless of whether it's talc that's being applied perineally or a talc that you're inhaling while you're

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applying it perineally, the fibers are still going to be present within that talc.
Q. Have you or anyone done an analysis of the dose of asbestos to which someone might be exposed perineally?
A. I haven't done a specific calculation, no.
Q. Has anyone done that calculation?
MS. PARFITT: Objection. Form.
QUESTIONS BY MS. BRANSCOME:
Q. That you have seen?
MS. PARFITT: Objection.
THE WITNESS: I'm trying to remember whether I saw that done in any of the documents related to Dr. Longo.
I don't know. I'd have to go look.
QUESTIONS BY MS. BRANSCOME:
Q. Okay. So as you sit here today, can you give an opinion to a scientific degree of certainty, reasonable degree of scientific certainty, that an individual would be exposed to a dose of

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asbestos above background through the perineal use of Johnson's talcum powder products?
MR. MEADOWS: Objection.
MS. PARFITT: Objection.
THE WITNESS: I don't think that's the opinion I have formed to date, but certainly the opinion I have formed is that the data I have seen indicates that you can't separate out talc without asbestos versus talc with asbestos in the information that's been collected. Because there's -- all -- the information that's been collected has shown there's no evidence that asbestos-free talc is available.
If by asking that question you're trying to say that it's the asbestos alone that's causing the cancer, that is not my opinion. So that is when the dose issue would become very important for asbestos.
QUESTIONS BY MS. BRANSCOME:
Q. Okay.

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A. So that's -- so that's a different question I have not answered.
Q. And in reaching your opinion that there is no evidence that asbestos-free talc exists, you have not been provided with the reports by the defense experts, including Dr. Matthew Sanchez, analyzing Johnson's talcum powder products for the presence or absence of asbestos, correct?
MS. PARFITT: Objection. Form.
I think you're aware that the MDL expert reports have not yet been provided to us.
MS. BRANSCOME: Yeah.
MS. PARFITT: I'm just making a point.
THE WITNESS: I have not seen a report by Dr. Sanchez. I assume I will, because typically after -- later in the litigation, once all experts have been deposed or revealed, I'm usually given defense expert reports and their deposition testimony. So I expect to see that; I just haven't seen it yet.

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QUESTIONS BY MS. BRANSCOME:
Q. And you haven't seen it in any of the cases in which you've rendered an opinion, correct, not just the MDL?
A. Well, none of the cases that I have worked in have involved the issue of looking for asbestos exposure.
The cases I have worked on have been talking about talc exposure that may include asbestos as a constituent, but it wasn't focused on asbestos exposure.
So, no, none of the cases I worked on have provided testimony in that area.
You understand what I'm saying?
Q. Let me just make it clear. You have not, in any of the cases in which you have offered opinions with respect to the contents of talc, been provided with an expert report or testimony by Dr. Sanchez about what he did or did not find in Johnson's talcum powder products with respect to asbestos?
MS. PARFITT: Objection. Form.
THE WITNESS: So I can't tell

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you that I have not. I don't recall it. That's all I can say. I don't recall that name.
QUESTIONS BY MS. BRANSCOME:
Q. It's certainly not something you discuss in your report, correct?
A. No, I do not. And I don't know that it's in my reliance materials. That's why I'd ask you to look there, because if it's in my reliance materials, then I've seen it.
Q. Okay.
A. And I mean big reliance material list, not my reference list.
Q. All right. With respect to the other potential constituents of talc, have you done any analysis to provide an answer as to how much -- what dose of chromium, for example, an individual might be exposed to through the perineal use of Johnson's talcum powder products over a lifetime?
A. No, and I have -- well, I know it's a separate deposition. We discussed this yesterday. No, I have not done a -- a calculation of a potential dose with perineal

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application for any of the heavy metals. So the three that I've mentioned, no, I have not done that calculation.
Q. You would agree, based on your training and experience as a toxicologist, that in order for an agent -- and we can talk specifically about a metal -- to present a risk of cancer it needs to be bioaccessible, correct?
A. If by bioaccessible you are not limiting that definition to solubilized into the blood and carried systematically, yes, I would agree with that. Bioaccessible meaning it has to be in a form that can somehow interact with the tissue, yes, I agree with that. But it could be as simple as tissue contact versus needing to be solubilized.
Q. Okay. Is silica bioaccessible?
A. It depends on the form of the silica. So silica particles can be bioaccessible if inhaled and found on the surface of the lung. That can cause injury at the site of the lung. So that's an accessibility to that particular tissue that it contacts.

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Q. We talked earlier -- it's somewhat related to bioaccessibility, but we talked about the way in which different particles might move specifically through the genital tract in women.
Do you recall that?
A. Yes. A general discussion.
Q. Yes.
And when you testified that starch and talc might not move at the same rate, do you have an opinion as to which might move more quickly through the tract?
A. I haven't formed that opinion, no.
Q. Okay. And do both talc and starch particles remain in the body for the same length of time?
A. I haven't done an analysis to see if the data tells us what the -- what the differences might be. I would expect there to be differences, which is what I told you earlier, because I would expect the starch to be able to be solubilized, where I would not necessarily expect the talc to act in that same manner.

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Q. Is cornstarch capable of causing an inflammatory process?
A. It can. It is -- but it is -- it's a different level of risk for inflammatory responses than is talc, just by its chemical nature.
Q. Have you done an analysis in your report that examines the differences between the inflammatory response that can be triggered by talc as opposed to cornstarch?
A. I haven't analyzed inflammatory response. Instead, what I've done is done a comparison of what the toxicity -- the differences in the toxicity potential have been described in medical literature, and I cite -- I have a paragraph where I cite to some sources that talk about the differences in the toxicity potential or biocompatibility of starch versus talc.
Q. Now, I had a question about your supplemental report that was marked as Exhibit 3 to the deposition.
At paragraph 67...
A. Okay.
Q. You identify here six heavy

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metals - arsenic, chromium, lead, cobalt, cadmium and nickel - that in your supplemental report dated August 29, 2018, you say have been reported across lots of talc powders.
Do you see that?
A. Are you in -- now you're in my MDL report or here?
Q. No.
A. Oh, so where are you? I'm sorry.
Q. Same report. It's the sentence that begins at the bottom of page 6.
A. Okay. Hold on.
About that they have varied at the levels --
Q. Yes. So you identify six different types of heavy metals.
Do you see that there?
A. Yes, I do.
Q. Okay. And the question I had for you was that in your report in the MDL, if you look at paragraph 36 --
A. Yes.
Q. -- you identify -- you identify

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only three heavy metals: chromium, cobalt and nickel.
Do you see that?
A. Yes.
Q. Why did you remove three of the heavy metals?
A. It's not so much removing. Those three heavy metals that I focused on in my MDL report are ones that have been talked about with a similar mechanism of action as far as irritation and biologic -- biologic plausibility mechanism being irritation and inflammation.
So that's why I focus on those three, which may not -- which is not necessarily the case for some of the others, even though they're also -- have a carcinogenic hazard, pose a risk.
Q. So in your -- as part of your risk assessment that you performed in the MDL, are you offering the opinion that to the extent they exist in any of the Johnson talcum powder products, that arsenic, lead --
A. Cadmium.
Q. -- and cadmium play any role in

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the risk of developing ovarian cancer?
A. That is not an opinion that I would be offering in the MDL.
Q. Okay. Now, you talk about these heavy metals having been classified by different agencies as either known probable or possible human carcinogens, correct?
A. You're in my MDL report again?
Q. Oh, yes.
A. Okay. I'm sorry. Okay. Let me get there.
Yeah, I do have that discussion. I'm just trying to find it.
Q. Sure.
A. Okay. Yes, I'm there.
Q. Is it your view, based on your expertise, that because a compound can cause one type of cancer, it can cause all types of cancer?
A. No, not necessarily. It depends on the -- well, it depends on a couple of things. It depends on what's been studied. Have all types of cancer even been studied. And then it also -- it also depends upon, I believe, the route of exposure as

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well. So can it get to where it could cause that, could it distribute there. And then in addition to that, what data has been collected. Is there enough data, for example, to show that there's extrapolation from animals to humans in the types of tumors or is it -- or if we have good human data, then we would focus on the types of cancers that you're seeing in humans, for example.

Q. Okay. But you recognize even where there is complete data some compounds can cause one type of cancer and they are incapable of causing another type, correct?

MS. PARFITT: Objection. Form.

THE WITNESS: I don't know about incapable, but I would agree that you certainly would see -- you could potentially see different observations.

If you're talking about animals versus humans, or are you talking about --

QUESTIONS BY MS. BRANSCOME:

Q. If humans.

A. Based on what you had seen in

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the animals; is that what you're asking me?

Q. Yes.

A. Yes. So, yes, there is not always a one-to-one concordance. So that's why -- that's why I made the comment that it's important to have some human data or experience, so that you can put in context the data you collected in animals.

I would say to you there are certain kinds of tumors in animals, for example, that are shown to be not relevant at all to human risk assessment. Like four stomach tumors in rats is an example. I've dealt with that one a lot.

Q. What types of cancer -- type or types of cancer are the basis for the classification of chromium as a known human carcinogen by IARC?

A. So I have to pull it out, but I believe that there may be some GI cancers and maybe some skin cancers, but I'm not sure. I've got it pull it out. It's been a while since I've looked at it.

Q. Okay. Have you done an analysis to evaluate whether or not the types

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you can extrapolate with scientific basis from one type of cancer cause to ovarian cancer with respect to the heavy metals specifically?

A. Well, I haven't attempted to that, because I haven't attempted to define a independent risk for each of those metals individually.

The issue -- the issue I have with those metals is -- there's a paragraph here where I talk about pathogenesis of carcinogenesis, where I talk about different stages of cancer development and the fact that inflammatory responses may be operating at all those different stages.

So the issue is you have potential -- you have compounds that are known to produce cancer or have been shown to have a potential risk of cancer. They share a similar mechanism to talc, so as a result of that, they factor into your risk assessment as far as there being an exposure to a mixture.

But on the issue of ovarian cancer, I'm looking at the data that's been

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collected on talc itself, which would be talc with the constituents that could include the metals. But certainly I'm not saying that it is -- without the presence of one or the other of these there would be no risk of ovarian cancer. I'm not saying that either.

Q. So my question is, though, can you point me either to scientific literature directly documenting that these heavy metals can cause ovarian cancer or to scientific literature that enables you to extrapolate from the types of cancer that they are known or believed to cause to ovarian cancer?

A. So I -- on the issue of can I point you to the data on ovarian cancer, I'd have to go back. I can't answer that without looking at the assessments.

But on the other -- second question you asked me, that's the question I was just trying to answer before. It's the idea that regardless of where the cancer is developing, the fact that these compounds have the ability to stimulate similar toxic responses in tissues could lead to a -- setting up a situation where the -- where the

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tissue is primed for cancer development.
Q. And do you have --
A. And so that --
Q. Sorry.
A. And that has to do with the basic science of carcinogenesis when you look at underlying mechanisms, especially with tissue contact, direct tissue contact, with irritants or inflammatory processes.
But I would -- I am not -- I have not formed the opinion, again, that with or without either one of these that I would expect ovarian cancer to be the target. I'm saying that ovarian cancer risk is increased based on exposure to talc, which includes a variety of constituents.
Q. Okay. And do you cite anywhere in your report to studies documenting -- I know you said you'd need to go look at them, but I'm asking if it's in your report anywhere a discussion of any studies showing that the particular heavy metals that you cite as potential constituents of Johnson & Johnson's products have been demonstrated to increase a risk for ovarian cancer on their

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own?
A. So, no, I haven't addressed that in my report. And again, I think that's inconsistent with the way I'm using these data. But that's fine. I mean, no, I haven't done a specific assessment of ovarian cancer risk with each of those metals individually.
Q. I would ask the same questions for the different fragrance constituents that you allege in your report are potential carcinogens.
Have you done any analysis, and can you point me to any scientific studies that establish that those particular compounds are capable of causing ovarian cancer?
A. No, I haven't done that analysis, but, again, general principles of toxicology and cancer risk assessment, when you look at the presence of multiple -- excuse me, multiple carcinogens with similar mechanisms of action, you would assume in your risk assessment that those risks could be additive.

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So, again, that's what I'm pointing to and why I have cited the data.
Q. Now, you talked about -- when we were discussing mechanism, you said that inflammation alone is not necessarily sufficient to cause cancer, correct?
A. Yes, I did.
Q. All right. Do you have scientific studies that show that any of the heavy metals or the fragrance constituents that you identify as potential carcinogens create -- generate phenotypic changes like you discussed were next for the formation of cancer?
A. I believe that data is available on nickel. I need to go back and look at chromium and cobalt, but I do believe with nickel you'll find similar data on tissue irritation and inflammatory processes.
Nickel is also a sensitizer, so it has interaction with the immune system, so I do believe that for nickel you can find some of that data.
Q. Okay. But as you sit here today, can you point me into any of that

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that's discussed in your report?
A. No specific discussion other than, again, all -- the IARC -- I'm citing to the IARC assessments, and the IARC assessments for each of those discuss carcinogenesis and a biologically plausible mechanism being linked to the ability of these compounds to induce oxidative stress and/or inflammatory processes.
Q. Okay. In your opinion, you talk about the mixture of constituents that are involved in talc.
Have you done any analysis to look at how the different constituents interact with each other?
A. Well, yes, that's my issue at looking at underlying mechanism.
But are you asking me -- I certainly don't have a -- the only studies that I have to rely upon on the interaction of the mixture is the actual studies on the powders themselves, where we know that the powders contain constituents other than just platy talc.
Q. Okay. And do the constituents

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need to have the same underlying potential carcinogenic mechanism for them to have an additive effect?

A. By general principles of toxicology, yes, you look at mode -- mode of action or mechanism of action before you apply that additivity principle to the cancer risk assessment.

Q. And so as you sit here, you believe there have been scientific documentation that nickel might operate through the same biological mechanism as you purport talc to operate, but you're not sure about the other heavy metals or the fragrance constituents; is that correct?

MS. PARFITT: Objection.

THE WITNESS: For the fragrance constituents, I'd definitely have to pull because I haven't looked at that individual assessment in a while.

For these three, what I do know is that they do share the ability to at least induce oxidative stress.

What I can't recall for chromium and for cobalt is whether

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they're taking it the next step from oxidative stress to inflammatory process. I believe that they do, but I'd have to check, whereas I know nickel has been shown to lead to an inflammatory process after oxidative stress has been induced.

QUESTIONS BY MS. BRANSCOME:

Q. And you would agree, even more than requiring an inflammatory process, you would actually have to see that these compounds can generate phenotypic changes, correct?

MS. PARFITT: Objection.

THE WITNESS: Well, we know they do because they've been shown to be carcinogenic. If you've been shown to be carcinogenic, you've done a phenotypic change in the cell from a normal cell to a cancer cell.

So we know they have the capability to induce tumors, or cancer, all three of those, at least in animals if not in humans as well, because two of them are known human.

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So those two -- we'd have human data to show that.

But on the issue of cobalt, it may only be -- I need to go back and look, but it may indeed just be animal data.

QUESTIONS BY MS. BRANSCOME:

Q. And so your basis for that would be the IARC classification?

Is that where I would go to look if I wanted to look at it after this deposition?

A. I'd go to the IARC reviews. I'd go to those three which I believe I have cited down here for you and given you where to go to find them.

Q. Okay. You discuss in your report -- and if you'd like to reference it, it's paragraph 69 on page 47 -- the concept of genotoxic and nongenotoxic carcinogens.

Do you recall that?

A. Yes.

Q. And as you sit here today, is it your opinion that talc is more likely a nongenotoxic carcinogen?

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A. As the direct insult, yes. And I would like to -- I would like to point out that in the literature -- the reason I have this paragraph here is because in the literature in the past, in the area of chemicals, it's been -- toxicologists have attempted to put two bins, direct genotoxic insult versus nondirect genotoxic. It doesn't mean you can't get a genotoxic event after the initiation.

So I want to make sure you understand that. I'm not saying that there is no possibility of this chemical in its -- in its process of inducing cancer leading to indirect genotoxicity, but I'm talking about the direct mechanism at the site of the cell.

So talc, for example, has been shown to not be genotoxic in cells. And so that's why I believe, then, when I look at the rest of the data that fits, that it fits the definition of a nongenotoxic carcinogen by its initial mechanisms to induce cancer.

Q. Okay. And if talc is, in fact, a nongenotoxic carcinogen, it would suggest that there is likely a threshold dose below

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which it does not have a carcinogenic effect, correct?
MS. PARFITT: Objection.
THE WITNESS: It is possible, and that's the problem. In order to fully assess that, you would have to have the data to prove it.
But that's the assumption. You assume with nongenotoxic carcinogens that you could identify a level where you wouldn't turn on that indirect mechanism. So that -- yes, that is true.
QUESTIONS BY MS. BRANSCOME:
Q. And you have not been able to identify, nor can you point to, scientific literature that identifies a threshold -- a threshold dose for talc with respect to its carcinogenic potential for ovarian cancer, correct?
A. Not a specific dose, but I think that's why I mentioned to you -- and I -- I think that's why Canada, when you look at their document, they talk about discouraging routine use generally. So it's

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the issue of what -- single use of a body powder or an occasional use is a different risk assessment than routine use.
So if you want to talk about thresholds that way, that's very imprecise, but you could do that. You can talk about whether or not there -- I do believe there's a different risk profile for one or two uses of talc body powder versus a risk profile of somebody who uses it routinely, because I think that fits that threshold definition. It's the idea that you have limited availability for enough particles to migrate to lead to the tissue toxicity that it cannot be recovered from or repair.
Q. You're familiar with the concept of the precautionary principle, correct?
A. Yes.
Q. All right. And you understand that Health Canada may have made recommendations with respect to product usage that are purely precautionary, correct?
MS. PARFITT: Objection. Form.
THE WITNESS: I disagree that's

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what they've done, but is it possible that they would do it? Any regulatory agency, it's possible they could do it, yes.
QUESTIONS BY MS. BRANSCOME:
Q. Do you have any information with respect to Health Canada's decision-making, other than what you have read on the face of the documents?
A. That is all I have to look at is what is provided on the website.
Q. Okay. And so the statement that you think Health Canada was suggesting a dose threshold by their statement of discouraging routine use, you're basing that entirely on what you read on the piece of paper, correct?
MS. PARFITT: Objection. Form.
THE WITNESS: Well, that's what they state. So, yes, I'm -- I am telling you what I see on their website. If that's what you're asking me, yes, that is true.
QUESTIONS BY MS. BRANSCOME:
Q. Okay. Can you point me --

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well, do you discuss -- have you looked at, as part of your opinion specifically in the MDL, the studies exploring a potential link between asbestos and ovarian cancer? Just asbestos.
A. Some of the studies, yes, but I have not -- I have not done a separate risk assessment just for asbestos by itself, because I have not assumed that there is asbestos-only exposure.
Does that make sense?
But I do cite -- for example, I cite to some of the early literature on -- so this -- I guess where this opinion comes in is on hazard and warning. So in the warnings I talk about when it was known that asbestos was linked with cancer, because the warning standard is not causation proven but the identification of the potential. And so that is in my report on warnings, but that is not within my discussion of the weight of the evidence for risk assessment of the talc product.
Q. Okay.
A. Does that make sense?

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Q. Uh-huh.
For example, have you rendered an opinion about what dose of asbestos exposure would be necessary to cause ovarian cancer in an individual?
A. No, I have not formed that opinion at this time.
Q. Okay. Do you have an opinion about the background level of asbestos to which individuals are exposed with no increased risk of any type of cancer?
A. No, I do not have an opinion. I do believe others do, but I do not.
Q. Okay. You may have been asked some of these questions before, but I will keep them brief.
Have you ever published any articles that state that talc causes ovarian cancer?
A. No, I have not.
Q. Have you ever publicly expressed the opinion that talc increases the risk of ovarian cancer outside of literature?
A. No. My work has been in the -- in the courtroom.

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MS. BRANSCOME: I think we can take a break.
VIDEOGRAPHER: We are going off the record at 2:57 p.m.
(Off the record at 2:57 p.m.)
VIDEOGRAPHER: We are back on the record at 3:13 p.m.
MS. BRANSCOME: Dr. Plunkett, I have no more questions for you on behalf of Johnson & Johnson, subject to your counsel doing a direct of any kind.
THE WITNESS: Sure. Thank you.
EXAMINATION
QUESTIONS BY MS. BOCKUS:
Q. Good afternoon, Dr. Plunkett. You and I have met before. My name is Jane Bockus, and as you know, I represent Imerys in this case.
A. Yes.
Q. Correct?
I want to go back to just touch briefly on a couple of issues that have already been addressed.
Would you agree that IARC has

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not classified any of the heavy metals that you've identified in your MDL report as carcinogenic to the ovary?
A. So the answer is I'd have to look. I don't recall that, but I'd have to look to confirm.
Q. Okay.
A. That's the answer I believe I gave a few minutes ago, yes.
Q. So if I look at the IARC website, then I can confirm whether or not they have identified any of those as carcinogenic to the ovary?
A. Not so much the web -- well, the website or the actual documents. I think I would actually point you to the actual monograph --
Q. To the monograph.
A. -- because there may be evidence in there of ovarian cancer as being seen in studies. And I'd have to go look.
Q. Okay. That was not part of your consideration here, correct?
A. So ovarian cancer is part of my consideration, but I didn't -- in this part

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of my evaluation I'm trying to -- trying to describe these metals. And this is really about mechanism of biologic plausibility and the fact that these two things can go together, and then the concept of additivity is they're on hazard. The idea if you have a cancer hazard generally and you have similar mode of action, regardless of the tissue, you would be expected to have a potential additive effect when you do a risk assessment.
So that's my use of that data, which is why I didn't do a separate ovarian cancer assessment for each of the each constituents but just on powder.
Q. And you discuss that topic on page 47, paragraph 68, of your report, correct, the -- whether there's an additive effect?
And you cite to Casarett and Doull. I don't know if I'm pronouncing those names correctly.
A. I'm sorry, on what page?
Q. I'm on page 47, paragraph 68.
A. Okay. Sorry. I should know

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where it is, but...
Okay. I'm there, yes. Okay.
Yes, I do cite to a chapter in Casarett and Doull, yes.
Q. Okay. And Casarett and Doull is a resource that you cite to for a couple of different toxicological principles that you discuss in your -- in your report, correct?
A. Yes, because it's one of the most well-recognized textbooks that is used across different either universities or schools or even in regulatory agencies.
I would also say I cite EPA 2000 there. I'm not citing just Casarett, but I am citing Casarett as well as an EPA guidance document.
Q. In Casarett and Doull, do they actually discuss talcum powder in Chapter 2, or is it more just the concept of the potential of the effects when you have two different chemicals that you're exposed to at once or three or four?
A. It's the latter. It's the -- because you'll notice the title is

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"Principles of Toxicology," so it's the general chapter teaching principles for risk assessment and toxicology as used in risk assessment.
Q. And whether there is an additive effect of, say, talc and nickel, that's something that an experiment could be designed to study, correct?
MS. PARFITT: Objection.
THE WITNESS: If you're talking generally for cancer and not worried about the issue of ovarian cancer, if you're talking about cancer, like doing an inhalation experiment to look what happens to the lung, that you could do.
The problem with the animal studies and ovarian cancer due to perineal exposure is it's very difficult to understand how you design a study to expose the animals that way reliably in the way that humans are exposed.
But generally you could study -- you might even be able to do

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a genetically susceptible mouse study to hurry the process along to look at, but you might not be able to do it through perineal exposure. You might have to do it through another route such as either inhalation or maybe even you could -- you could look at it through intraperitoneal injections, for example.
QUESTIONS BY MS. BOCKUS:
Q. Well, and what the textbook talks about is the fact that you need to study it to find out whether the effects are additive, whether the effects are something that multiply the risk, you know, so that the two together are greater than either one alone, or do the effects offset each other and reduce the risk, correct?
A. That is discussed there --
MS. PARFITT: Objection.
THE WITNESS: -- which is why I've cited the EPA document. Because the EPA document addresses the issue of mixtures, and this is the issue of mode of action. If you have chemicals

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that you're looking at on the issue of additivity or no effect, you will -- you look at that issue of how they're affecting the tissue and underlying mechanism.
But the only way to look at the magnitude absolutely of how the risk would change is by doing an experiment. That is true.
QUESTIONS BY MS. BOCKUS:
Q. And to your knowledge, that experiment has never been done; is that correct?
A. I can't guarantee that it's only been done for nickel and talc alone, but I would -- I would state that based on -- there are studies out there that have been done where they've used the body powder that we know have metals -- a variety of things within it that are not just platy talc, but those experiments are that kind of data.
But as far as gathering dose-response information or teasing out individual components, that is not available.
Q. Do you agree that dose response

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is the fundamental principle of toxicology that underpins the effects that chemicals can have on living organisms?
A. When you're talking general toxicology, yes, I think it's talked about in the textbook.
Q. And you agree that it is the dose of the chemical and the pattern of exposure that determines whether a chemical produces an adverse effect on an organism, not simply the presence of the chemical?
A. For a typical dose-response relationship for non -- for nongenotoxic events, absolutely, I would agree that is probably true. And I don't mean nongeno -- noncancer events.
In the issue of cancer biology, some of those issues don't hold all the time. In other words, there are certain chemicals and certain ways of looking at cancer risk assessment where you can't assume where the threshold is or identify what a safe dose would be. But certainly I agree on the issue of noncancer risk assessment generally, or general end points of toxicity, that is true.

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Q. And again, do you agree that in general toxicology the effects that might be reported at high doses will not occur at lower doses if the concentration at the site of action falls below the threshold for toxicity?
A. Yes, that could -- that could be possible, yes.
Q. And do you agree that evidence-based toxicology and epidemiology dictates that the dose of the chemical is the critical factor when examining the risk posed by a chemical, not just its presence even in the human body?
A. I would say that's generally true, yes, which is why I have attempted to look at the dose-response relationship as well as the prevalence of the contact.
Q. And with regard to the human studies that you cite, would you agree that none of the studies that you cite in your report that have to do with migration of particles within the genital tract of the female involve applications to the perineum or outside of the genital tract?

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A. That is true with the exception of Parmley and Woodruff, which addresses this issue of --
MS. PARFITT: Objection.
THE WITNESS: Talks about the issue of exposure from the outside to the inside.
But the data that is collected with the different studies they have deposited at some point -- at some position within the vagina, that is true.
QUESTIONS BY MS. BOCKUS:
Q. And that is not how talc is deposited in women who use it regularly in their daily routine, correct?
MS. PARFITT: Objection. Misstates the evidence.
THE WITNESS: So I would say that depends on what women are doing. Perineal application, for example, application on the underwear, can lead to contact of the vaginal opening depending on the woman.
For example, a woman who has

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a -- had many children has a tract that is stretched. There, indeed, you can have more direct contact than you can with a very tight -- so I would say it depends on the woman and it depends on the situation.
But I do think it's generally accepted, based on my review of the literature, that there is the opportunity for exposure internally from perineal application.
QUESTIONS BY MS. BOCKUS:
Q. And if I understand what you testified to earlier today and yesterday, you don't have any data that would advise on -- out of the talc that is deposited in the underwear, what percentage of it makes it into the reproductive tract?
A. That's the data that's missing, that is true. And unfortunately, no one has done a study. It would be -- if there was a way to do that, it would be interesting to do that. I just don't see how you design that study, especially knowing the hazard of talc at this point. I think that would be a

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difficult study to get approval for.
Q. And do you have an opinion as to whether it is even correct that each day that a woman uses talc in her underwear, that some of the talc makes its way to the ovary?
MS. PARFITT: Objection. Form.
THE WITNESS: Have I -- can I quantify that?
No, I haven't quantified it. I think I got asked that earlier. I can't quantify the amount that gets there. Or, I'm sorry, I may have misheard the start of your question. I apologize.
QUESTIONS BY MS. BOCKUS:
Q. Yeah, I'm really asking: Do you have an opinion as to whether it happens every single time a woman applies talc to her perineal area? Does some of that talc make it to her ovary?
MR. MEADOWS: Objection.
MS. PARFITT: Objection.
THE WITNESS: I don't think I stated it quite that way, but certainly I think the opportunity is

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there with every application. And of course it would depend upon the amount of time that the contact may be in place. But the opportunity is there.
So, for example, if you applied it to your underwear and 30 minutes later you go to the bathroom, it's very possible that you will have wiped away, and so that that application may have taken an opportunity away. But I do believe that the opportunity is there based on the literature I have seen.
And so I haven't formed the opinion, though, that it's absolutely every time. My opinion, I think, is based on the fact that I believe that there is data to indicate that exposure occurs, and that with routine, continual habit, sort of a habit exposure, that indeed that there was some migration that occurs.
QUESTIONS BY MS. BOCKUS:
Q. And is it fair to say that you don't have an opinion as to whether that

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migration occurs every day, once a week, once a month?
MS. PARFITT: Objection. Form.
THE WITNESS: I haven't formulated my point -- my opinion quite that way; however, I do believe that it is something that is going to happen routinely with exposure. I do believe that migration is something that is going on routinely with application.
So with applications, I do believe that that is, but I can't tell you that this amount has migrated on this particular day with this particular application, no. That -- the data that we have collected is not there to allow us to do that.
QUESTIONS BY MS. BOCKUS:
Q. How do you define the word "routinely" as you're using it in that answer?
A. So that would be the idea of repeated exposures, you know, within a week, within a month, within a year. So not --

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routine to me would not be -- would not be applying it once a month one month, waiting six months, doing it again, and then not doing it until the next year.
Again, it's the idea -- some people may -- routine may be during the hot season of the year, they're routinely getting daily exposures when it's warm, and during the cold weather not applying. But then the next year doing -- that's a routine for them and their habits based on their pattern of exposure.
Again, we know that talc, when it -- when it migrates and gets into the body, we have data to show that it is -- it is able to persist in the body. The fact that you may have not been exposed for three months because it was cold doesn't mean that you -- that that changes the fact that you're still at risk with additional exposures the next -- the next time that that habit becomes -- comes into place.
So I think there's multiple exposure patterns that are possible, but when I use routine, it's something that people are

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doing throughout their -- a period of their life. And so it would be something that happens either on a weekly basis for a good part of the year. I haven't defined it with a particular number, though, no.

Q. And my question had to do with out of the number of times a given woman -- or an average woman uses talc, what percentage of the time does talc make its way into her reproductive tract?

A. So I don't think that anybody -- anybody can point to a piece of data that tells you that, but, again, it's based upon the anatomy, I would expect there to be the potential each time it's applied.

And on your question on routine, when I'm talking routine, I'm looking at not just frequency but also duration. So when I'm talking about dose, it's the fact that they do it on a repeated basis for a number of -- a period of years as well.

That's what the data shows in the human studies. It's not something, again, that may have been done routinely for

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one year, but it does appear to be something that's done more -- longer term than that.

But we can't give a number. We have no threshold. We don't know exactly what that minimum number is.

Q. Do you think that the minimum number is greater than a year?

MS. PARFITT: Objection. Form.

THE WITNESS: I haven't formed that opinion, no.

QUESTIONS BY MS. BOCKUS:

Q. Do you think it's greater than a month?

MR. MEADOWS: Objection.

THE WITNESS: Greater than a month?

QUESTIONS BY MS. BOCKUS:

Q. Yes.

A. One month in their life?

Q. One month in their life, where they're using it every day for a month.

A. So I haven't formed that opinion at this point in time, but I'd say it's more likely to occur when you do it more than a month. But I haven't formed an

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opinion on a set number, no. I can't -- can't point you a specific number.

I'm not doing case-specific, so I've not looked at any of those pieces of information for any given plaintiff.

Q. And I'm just trying to get the threshold.

A. Uh-huh.

Q. As I understand it, that is part of a toxicological evaluation, is the threshold below which there's not an issue.

So I think you've said you don't know if it's less than a year, but you think it's more likely than not that it's greater than one month.

MR. MEADOWS: Objection.

QUESTIONS BY MS. BOCKUS:

Q. Is that fair?

A. No, that's not exactly what I'm saying. I'm saying we don't know the threshold. So as a result, I'm not of the opinion that it absolutely can't -- it only has to be this long.

What I'm saying to you is per general principles of toxicology and based on

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the human data that we have, it indicates that it's more frequent than just one month, but I can't tell you that it's absolutely not possible.

That's where -- I do think when you're talking about those kinds of patterns, that's a case-specific issue for individuals, because I think that would have to be considered for each individual. But certainly as a toxicologist, I'm using the words "routine," "repeated," "longer duration," "chronic exposure." And when I defined "chronic" earlier, I talked about years of exposure versus just one month.

That would be consistent with what I have said, yes, but I'm not -- I -- I certainly don't want to rule out that there couldn't be somebody out there that could show something different, because it may very well be that there are people that you can identify with the presence of talc in their ovaries and all of their other case-specific things that could -- could make that pattern a -- make someone be able to draw a case-specific, reliable conclusion.

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But that's not my role. I don't do case-specific.
Q. And I am simply trying to get the parameters of your opinions with regard to the amount of talc use one would need to have before you would feel comfortable -- well, that in your opinion would be sufficient to create a toxic environment.
MR. MEADOWS: Objection.
THE WITNESS: Well, that's a different question. So toxic environment could be with a much shorter time exposure, okay?
QUESTIONS BY MS. BOCKUS:
Q. Right.
A. So but if you're talking about -- the opinion that I have formed has to do with an increased risk of ovarian cancer. So with that opinion, that's the description, I believe, I was giving this morning. It's the idea that the data that I've seen indicates that my opinion that perineal use of talc body powder products increases your risk for ovarian cancer above that background level that you know exists.

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That opinion is based on data that is -- is -- the supporting data would indicate that it has to be a habit, routine, a chronic exposure. And so as a toxicologist, I've tried to put that in context.
I don't know what else to tell you. That's the opinions I have formed to date.
Q. A chronic -- a habit, routine, a chronic exposure for years?
A. Well, chronic --
MR. MEADOWS: Objection.
THE WITNESS: -- is defined as years, typically, by a toxicologist, and so that's what I -- that's what I told you.
QUESTIONS BY MS. BOCKUS:
Q. Shifting to your regulatory opinions, you would agree that Imerys is a raw material supplier to J&J; is that correct?
MR. MEADOWS: Objection.
THE WITNESS: I would call them an ingredient supplier, yes.

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QUESTIONS BY MS. BOCKUS:
Q. Okay. An ingredient supplier.
And you agree that Imerys does not sell any products to the general public, correct?
MR. MEADOWS: Objection.
THE WITNESS: I don't know that's definitely true, but I'm not aware that they do.
QUESTIONS BY MS. BOCKUS:
Q. And what Imerys supplies to Johnson & Johnson is not a finished cosmetic that is ready to be sold on the market, correct?
MR. MEADOWS: Objection.
MS. PARFITT: Objection.
THE WITNESS: I don't know that I can answer that except in the context of Johnson & Johnson's baby powder, SHOWER TO SHOWER® and Shimmer, it's my understanding that Johnson & Johnson mixes -- has some fragrance added to the talc.
I don't believe Imerys does that, but I don't know for sure.

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So based on what I know -- I'm telling you what I know, and I would call them, again, an ingredient supplier, and I would call Johnson & Johnson a cosmetic manufacturer.
Does that answer the question?
QUESTIONS BY MS. BOCKUS:
Q. It does.
Would you agree that the minerals that you have identified in your report, that the documents that you have seen, would classify their -- to the extent that they are ever in the powder, that they're trace ingredients?
MS. PARFITT: Objection.
MR. MEADOWS: Objection.
THE WITNESS: So which ingredients are you referring to?
So some of the metals, no, are not trace ingredients.
Are you talking about the -- are you talking about the -- like the presence of tremolite or the presence of chrysotile --

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QUESTIONS BY MS. BOCKUS:
Q. No. No, I'm sorry. I'm talking about the three metals that you identify in your report. Those are trace elements that are -- that are sometimes detected in the studies of the -- of the talc.
MR. MEADOWS: Objection.
THE WITNESS: It's not how I would say it. I would say they're heavy metal components that are naturally occurring within the product that are sometimes -- sometimes detectable at levels that are reported as trace based on the detection limit within the analysis, but at other times they're not listed as trace. They're actually listed with a specific amount.
So that's what -- how I would define what I call trace. Usually that's how it will be reported in the lab, trace, which means below the limit of quantification, but it's there. You're detecting it.

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I would agree that -- that there are other descriptions of heavy metals in the heavy metal literature that talk about trace amounts being found in -- naturally occurring in food, for example, and I agree that that does occur. But in the case of this product, we actually have often -- we actually have a -- a limit that is set for acceptability in the specification.
And so I would think it's more proper to call it a level of the heavy metal that is allowable by the purity specifications set by the product. And sometimes those levels may be above, and most of the times those levels are below, which is why it's cleared. Because I've seen some analyses where different products may have been, I guess, turned away or considered not acceptable based on the analysis of certain types of minerals or metals.

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QUESTIONS BY MS. BOCKUS:
Q. Have you seen any studies where women's blood has reflected the presence of nickel or cobalt or chromium?
MR. MEADOWS: Objection.
QUESTIONS BY MS. BOCKUS:
Q. Who are parts of these studies -- these ovarian cancer studies?
MR. MEADOWS: Objection.
THE WITNESS: The epidemiological literature you're asking me?
QUESTIONS BY MS. BOCKUS:
Q. Yes, ma'am.
A. It's possible in the Nurses' Health Study that we can go to that, because I know they do collect some heavy metal levels. I've done that for other clients on other issues.
Most of the others, I doubt that we have heavy metal levels in blood. But certainly there are levels of heavy metal in blood, especially things like lead, for example, that we have very limited capacity to eliminate.

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So whether or not you carry around a significant body burden of a heavy metal in your blood is somewhat driven by the exposure pattern you get. It's something that's commonly -- or can you excrete it quickly or not. So...
Q. And are you familiar with any studies that have suggested that the use of body powders leads to a heavy burden of nickel, chromium or cobalt in the blood?
A. So I have not seen such analysis done, no, I have not.
Q. In paragraph 67 of your report, which is on page 46 -- I'm sorry, on -- oh, I'm sorry. Paragraph 64, I apologize.
A. No. No, that's fine.
Q. It's on page 44.
You cite to two abstracts --
A. Yes.
Q. -- one by Fletcher and one by Fletcher and Saed.
Do you consider these abstracts to be reliable sources of data?
A. They're not as reliable at all as a peer-reviewed article. So there's a

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difference in the weight you give an abstract, absolutely.

However, knowing the papers that Dr. Saed has actually published in the peer-reviewed literature, I have -- I have mentioned them in here because I do believe that they are -- they are pieces of information that are highly relevant to some of the issues raised in other cellular studies, and so that's why they're here. But certainly I do not give them the same weight as in my assessment of overall risk.

And I would say that I had the same opinions on risk before I had these studies. Because in my original reports, obviously, I have gone further than risk and talked about cause, and I didn't have the Fletcher studies.

The Fletcher studies are more on the issue of biologic plausibility and mechanism versus being important underpinnings, for example, for a hazard assessment.

Q. Is there any way that someone reading your report could tell that you

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attribute less weight to the abstracts by Saed and Fletcher just by reading your report?

MR. MEADOWS: Objection.

THE WITNESS: I don't know if they could or not. Hopefully they would based upon where they appear in the report. They're not cited a lot of other places, but they certainly are cited.

So that's why I'm here today, though. You're asking me these questions; I'm telling you. That's how I look at these studies. That's all I can say.

I haven't -- I haven't, certainly, as I've told you, given things numerical weight throughout my report.

QUESTIONS BY MS. BOCKUS:

Q. Looking at paragraph 118...

Well, when you were preparing your report, were you careful with the language that you used in it to be precise and accurate?

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A. I attempted to do that. I can't tell that you there isn't something in here I've missed. But, yes, I read this report six or seven times before I finalized it, trying to make sure that the language I was using was an accurate reflection of the opinion I'm expressing.

But it's possible, if you want to point to something that you want to ask me about, I can tell you whether or not that was something that I would change.

Q. So on page 77, paragraph 118 in the middle of it, you say, "Based on the knowledge available by the 1950s, talc body powders manufactured and sold by Imerys and Johnson & Johnson."

And that's the question that I have for you.

A. I see what you're saying.

Q. Was Imerys selling anything to Johnson & Johnson in the 1950s?

MR. MEADOWS: Objection.

THE WITNESS: I'm thinking. It's possible they did not. That may be true.

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QUESTIONS BY MS. BOCKUS:

Q. Well, and actually --

A. You know what? When I wrote this sentence, I assumed that they did, but if that is not true, then certainly this sentence should be just Johnson & Johnson.

Q. Well, earlier in your report, in a footnote you indicate that Imerys began supplying talc to Johnson & Johnson in 1989 or the late 1980s.

Do you remember making that notation?

A. So let me look. So if that's an inconsistency, then that should change. Let me look.

Q. And that's all I want to know, if it's an inconsistency, should it change.

A. If it is an inconsistency -- certainly if Imerys was not selling talc to Johnson & Johnson in 19 -- the 1950s, then -- then certainly Johnson & Johnson's products would not -- would not be affected by Imerys' activity.

However, if Imerys is selling talc to anyone that makes a consumer product

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in the 1950s, then -- or a precursor company to Imerys is making talc that's selling for body powder to somebody other than Johnson & Johnson, then that opinion would still hold.

So -- but I certainly agree, I think I -- you're right, I think I have a statement about the link between the two in '89. So in that case, then certainly the -- the link here would be related to Johnson & Johnson's products.

Q. Okay. Yeah.

A. Whether or not -- if they weren't sourced from Imerys, then that's a separate duty on a product, not this product.

Q. If you look on the bottom of page 7, I think you'll see the footnote I was referencing.

And with regard to your last answer, you don't have any information as to whether Imerys existed and, if it did, what -- who its customers were in 1950s, correct?

A. I don't believe I do, no.

MS. BOCKUS: I think that's all that I have. Thank you.

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MR. LOCKE: I've got a few questions.

EXAMINATION

QUESTIONS BY MR. LOCKE:

Q. Doctor, my name's Tom Locke. I represent the Personal Care Products Council. We met a couple of times before, I think.

A. I apologize, I don't recall your name at least. The face looked familiar, though. I apologize.

Q. I try to maintain a low profile.

I have relatively few questions. I wanted to ask you overall about your opinion.

Would you agree that reasonable scientists can disagree with your opinion that talc increases the risk of ovarian cancer?

A. I'd say I wouldn't say it quite that way. I'd say that I agree that scientists can disagree on conclusions they draw, depending on the -- depending on the way that they have assessed.

So certainly based on a

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complete assessment the way I did, then I would agree that other people could come to a different conclusion, absolutely.

So I think it depends what you mean by "reasonable scientist." But I would agree that individuals can look at the same body of data and, based on their judgment and experience, based on looking at that same body of data, could come to a different conclusion, yes. That's true.

Q. You've been involved in this talc litigation for at least a couple of years, right?

A. Yes.

Q. And you know that various defendants have offered experts who disagree with your conclusions, right?

A. Some of my conclusions, yes. I don't know that there is somebody that's in the litigation that does exactly what I do across all the opinions I've expressed, but, yes, certain parts of my opinions there are other experts I'm aware of, yes.

Q. Well, they -- you're aware that there are defense experts who disagree with

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your opinion that talc increases the risk of ovarian cancer; is that correct?

A. Yes, I -- I am aware of that fact.

Q. And in your review of the records that go back or the scientific materials that go back 35 years or more, you've seen that there's disagreement regarding that issue; is that correct?

A. So what documents are you referring to? Are you asking me about a specific -- just the published medical literature? Are you asking about documents like internal company documents, reviews by others? What are you asking me about?

Q. Well, let's focus on the published medical literature.

There are scientists who have disagreed with your opinion; is that correct?

MS. PARFITT: Objection.

THE WITNESS: I'm not aware of a paper in the published medical literature that has done the exact assessment I have done.

So I am aware of the fact,

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however, that there are individual papers by scientists that, for example, have concluded that there is no association between exposure to talc perineally and ovarian cancer, yes. Individual papers, I am aware of that, but that's different than what I have done.

QUESTIONS BY MR. LOCKE:

Q. Let me just ask you about what you were requested to do on behalf of plaintiff's counsel.

Plaintiff's counsel asked you to provide opinions related to the human health hazards posed by exposure to talcum powder products and how those hazards relate to the regulatory requirements for marketing cosmetic ingredients and cosmetic products in the United States; is that correct?

MR. MEADOWS: Objection.

THE WITNESS: I didn't write that, but that sounds like an accurate reflection of what -- what we -- what I have done at least in parts of my report, yes.

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QUESTIONS BY MR. LOCKE:

Q. Well, if you look at your report, I think you go to part where you were asked to provide -- and I just pulled it from what you said.

A. So I did write it, I apologize. It didn't sound like me.

Q. It started with "to provide opinions related to the human health hazards" and so forth, so I just wanted to make sure we're clear on that.

A. Sure.

Q. So does that sound right in terms of what you were asked to do?

A. I said I -- certainly those are the kinds of things that I was definitely asked to do. I was asked to do two basic -- two basic things, which was having to do with toxicology and risk assessment, and then a separate issue related to regulatory concerns.

So, yes, those are the two basic, I guess, buckets of information and documents that I reviewed and opinions I've expressed, and I think that's consistent with

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what I've been doing in the litigation.

Q. Okay. As to that second bucket, the US regulatory requirements for marketing cosmetic ingredients and products, that's not relevant to the scientific question whether talc may cause ovarian cancer; am I right?

A. No. I disagree with that based on the fact that a company that markets a cosmetic product is required to do a safety assessment. And if in that safety assessment issues relate to cancer or ovarian cancer and the use of talc, then those two things are related.

But I would agree that -- that doing a risk assessment like I've done is a separate issue from doing a safety assessment for a product, because there's actually even a lesser standard for an issue of looking at a safety assessment for a product versus actually forming the opinion that there is an increased risk of cancer with exposure to talc.

Q. Now, did IARC in 2006, did it look at the US regulatory process in

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considering whether talc may cause ovarian cancer?

MR. MEADOWS: Objection.

THE WITNESS: I don't think I understand what you mean. It's not a US regulatory process, no, if that's what you're asking me.

They have a -- they have a discussion of what the products are, which is part of the way they're sold. But I don't think they're discussing the duty of a company under the regulatory process, no, that's a separate issue.

QUESTIONS BY MR. LOCKE:

Q. So their analysis of whether talc may cause ovarian cancer, that's different than the analysis of whether a company may have a duty, whatever that duty may be?

MR. MEADOWS: Objection.

THE WITNESS: It's a different process, absolutely. IARC is a separate, independent body that does an assessment looking at the issue of

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cancer hazard and looking at whether or not there is sufficient evidence to categorize that hazard, whereas a duty of a company under the regulatory situation is broader than just cancer hazard; it's a whole different thing. It's what you do internally before you market a product. Totally different.

And so certainly when I -- that's why I have separate sections in my report, and that's why I even have -- I've had discussions about the difference between the regulatory standard for warning versus the assessment of risk that may be required in order to start to produce a -- identify a association or an increased risk or even if you did a causation analysis. Totally different type of exercise.

QUESTIONS BY MR. LOCKE:

Q. Do you first, in that exercise, look at the scientific issue of whether talc may cause ovarian cancer?

A. Are you asking me in either of

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these exercises?

Q. Well, let's say when you're getting to -- you mentioned the duty to warn. So if you're looking at the duty to warn, do you first have to look at does talc cause ovarian cancer?

MR. MEADOWS: Objection.

THE WITNESS: That's not the question you asked. No. I would argue, based on the regulations, if you look at the standard, the question is, is there evidence to indicate that there is a chance, there is a potential -- not that it does, but is there a potential for that type of hazard to be posed to consumers who use the product.

It's a possibility versus being a -- I'm taking it beyond possibility when I'm doing my assessment for increased risk. And I talked about that this morning, and I can't remember her last name. The Johnson -- I apologize. But I -- with Johnson & Johnson. I talked about

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this is a different assessment and different standard. It's a much lower standard on cosmetics for what needs to be done as far as warning.

Now, when a company comes and initiates a safety assessment on their product, before they even think about what am I going to warn, they should be doing a comprehensive assessment of safety based on what's available publicly, knowing what others have reported and then what data they've collected.

If they don't have data at all on the safety of the product, then the product has to say that. We don't know. We do not know if this product is safe. And that's one of the things that is allowed under FDA -- under FDA regulations as well.

But essentially some -- some assessment must be done to understand from the perspective of the company that this product is safe for consumers to use as -- under the

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directions of use.

So in the case of this, it would be a body powder being used on the body surface but also perineally because -- because that was an exposure pattern that was understood.

QUESTIONS BY MR. LOCKE:

Q. Okay. You described two different buckets. They're independent assessments; is that correct?

MR. MEADOWS: Objection.

THE WITNESS: Initially that's where I started, and now I'm talking two different duties. There's a duty to warn, but there's first a duty to collect information before you market it. It's your premarket safety assessment.

QUESTIONS BY MR. LOCKE:

Q. Okay. I'm not actually talking about the manufacturer's duty. I wanted to just first address your scientific analysis.

That's a separate question that led you to your opinion on the -- your opinion that talc increases the risk of

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ovarian cancer, correct?
MR. MEADOWS: Objection.
THE WITNESS: Yes, that's what I described. And I thought you were talking about duty of the company, and so I apologize. I didn't mean to go off on a tangent.
If you want to focus just on the risk assessment -- is that what you want to do? -- that's what I'm doing.
QUESTIONS BY MR. LOCKE:
Q. No, I just want to understand, those are two different things, though, right?
A. Those are two different -- those are two different tasks that I undertook, yes. I undertook a risk assessment task to form opinions based on what I can say about risk, and then I separately -- and I had done this earlier on the issue of warnings, looking at what do we know about the product and whether or not -- and when did we know it, and what should consumers have been warned about based on the

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safety information that was available over time.
Q. The risk assessment task, that's what you mean by your analysis that talc increases the risk of ovarian cancer?
A. That's correct.
Q. You could have stopped at that, but then you performed an additional task; is that right?
A. Well, actually, no, because the first task I actually started with was the regulatory task. When I first started getting involved in the litigation very -- before I wrote my first report, one of the first things I was looking at was the issue of the duty of the manufacturer to provide warnings.
And then after that, I expanded that role to be an inclusion as well of a causation analysis.
And then now I'm not doing a full causation analysis in this litigation, but I'm using essentially some of the same information to provide you with a description of a -- a health risk assessment, which was

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also sort of -- that's a piece along the way to doing a causation analysis, but it's not the same.
Q. Your opinion regarding the FDA's responsibilities and functions, that's not related to your opinion that talc may cause an increased risk in ovarian cancer; is that correct?
MR. MEADOWS: Objection.
THE WITNESS: I don't think that's true the way you're asking that question, because I don't know how you divorce the fact that as a -- in a regulatory assessment, if I identify cancer hazard, I have identified a duty to warn. That's certainly something that should be warned about when I understand that there's not only the potential, but I believe there's an increased risk.
But I would agree with you that in my report, I'm laying out for you even different bodies of information that -- as I step through it.
Does that make sense to you?

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QUESTIONS BY MR. LOCKE:
Q. Not really.
A. I'm sorry.
Q. I'm talking about your scientific analysis here, not your regulatory analysis.
To do your scientific analysis, you looked at scientific materials, right?
A. Yes, but I do the same thing for my regulatory analysis. That's why I'm confused. I -- to me they are connected.
But I would agree with you, I had an analysis. Let's just talk about that, my analysis on risk assessment and my opinions that I've expressed. Those are laid out in a separate section of my report, absolutely. So we could talk about that if you'd like.
Q. Well, I just want to understand, and I think I do now, that's a separate issue from your regulatory opinion?
A. It's not a separate issue. That's where I'm having trouble with your language.
It's a separate task because,

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for example, I may have only been asked, but I wasn't, to just describe whether or not, as a human risk assessor and toxicologist, there is a hazard or a risk posed by the product, and I could stop there.

But I was asked, based on -- based on my experience working in the area of regulatory toxicology but also on regulatory issues for clients where I give advice, I was asked to look at how does that scientific information impact what the company should be doing.

And so that's -- that's why I'm saying you can't divorce them, because the warning issue I'm talking about is intimately tied into the human health risk assessment results.

Q. So do you consider yourself primarily here as a warning expert?

MR. MEADOWS: Objection.

THE WITNESS: I consider that one of my roles, yes, absolutely.

It depends upon how individual cases, individual attorneys, will -- will ask -- decide to use me. For

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example, I have been used in one trial to only talk about the toxicology. Other trials, I've talked about toxicology as well as regulatory issues. So I think it just depends on the case.

In the MDL, I am prepared, however, to come to talk at a trial on the regulatory system that guides cosmetics as well as provide opinions that talk about what are the hazards of talc, what is the toxicology of talc, what do -- how can you be exposed to talc, that migration issue, and then my opinions about whether or not I believe that there is an increased risk of ovarian cancer.

So I would be -- be prepared to talk about both of those things. That's why I said I do think I'm a little different than some of the other experts that you may encounter, for example, in the defense side, where someone may just do regulatory or somebody may just do toxicology.

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But I practice in both those areas in my consulting practice and in my experience.

QUESTIONS BY MR. LOCKE:

Q. Let me ask you a few questions about your cosmetic ingredient review statements, CIR.

We can agree to call it that, right?

A. Yes, that's fine.

Q. In parts of your report, you cite the CIR as an authoritative source on cosmetic ingredients; is that correct?

A. So where are you looking at, the background information on the CIR?

Yes, they certainly are a source of information that FDA relies upon as far as assessments, yes, that's true.

Q. Well, and on page -- or paragraph 35, page 23, you cite to the CIR on, for example, chemicals purportedly in cosmetics. You have a footnote there.

A. So --

Q. I believe it's footnote 31.

A. Yes, I have looked at -- looked

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at the CIR as a source of information because many of the chemicals, many of the ingredients within the fragrance of Johnson & Johnson, the only available information may be found within the CIR that's publicly available.

Q. And you rely on the report of Dr. Cralley; is that correct?

MR. MEADOWS: Objection.

MS. PARFITT: Objection.

QUESTIONS BY MR. LOCKE:

Q. You reference Appendix D to your report. I believe if you stay on the same page you'll see that, the same paragraph.

A. I wouldn't say I rely on the report of Dr. Cralley because I form my opinions independent of Dr. Cralley, but certainly his -- I believe if you go to his reports, his report is supportive of my opinions in this area.

Q. Did you read his report?

A. I have read it now, but I did not read it before I -- before I formed my opinions in this particular paragraph, yes.

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Q. I'm a little confused because you're citing to his report.
You read it or you didn't read it before you wrote this paragraph?
A. I read it before I wrote the paragraph. I didn't read it before I had formed the opinion. Do you understand what I'm saying?
I did my review of the irritant chemicals independently before I looked at Dr. Cralley's report. So I had formed the opinion that -- of the chemicals I had searched for that this is what I identified. And that's what this is talking about, right?
I'm saying here that of the more than 100 chemicals included, over 70 percent are compounds linked with some level of irritant hazard. That was done on my own.
Then, if you go to look at Dr. Cralley's report, I cite it here because it's consistent. That is, his report provides support additionally for the statement I'm making.
So I'm not relying on his

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conclusions to make my opinion, but it's certainly -- I am citing it here as it being a piece of evidence that is consistent with my opinions.
Q. Sorry, I seem to have messed up my microphone. I'll try to hold it for a little bit then.
Do you disagree with Dr. Cralley's report?
A. I have not formed an opinion that I agree or disagree. He -- with his -- I believe he has information that is consistent with the opinion I'm expressing in the sentence, however.
Q. And do you know that Dr. Cralley repeatedly cites to the CIR as an authoritative source regarding cosmetic ingredients?
A. I don't know that he uses that exact language, but he does cite to it, yes, in his report. Certainly he does.
Q. More than 20 times, right?
A. That, I have not counted. I can't tell you that. But he does, just like I do, as a source of information when there

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is no other source available.
Q. Okay. In your report you state that the CIR process is administered independent of the FDA.
But the FDA is on the CIR steering committee; is that correct?
A. That is correct.
Q. You don't mention that in your report, although you mention others who were on the CIR steering committee, correct?
A. Yes, there's a paragraph where I talk about others, yes.
Q. But you don't mention that the FDA is on the steering committee?
A. I believe I -- I believe I've been asked that question before, and I said yes, but certainly in this report I don't believe I state that, that is true.
Q. CIR solicits input from the public; is that correct?
MS. PARFITT: Objection.
THE WITNESS: I would say they solicit input from industry, yes.
QUESTIONS BY MR. LOCKE:
Q. Well --

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A. But they -- and they do have a public comment period, which is mainly input from industry.
But I agree that they do -- and if what you're referring to is a public comment period, yes, there is that for the documents.
Q. You can go on the website and see what ingredients CIR is going to review, right?
A. Yes, you can.
Q. Have you done that?
A. Yes, I've done it many times before.
Q. Okay. And did you submit comments on talc in 2012?
A. No, I did not.
Q. Okay. You could -- the public can submit comments many times during the process of an ingredient review; is that correct?
A. There are different -- different stages of the draft document. Is that what you're asking me? Yes, that can be done.

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Q. Well, even before it's a draft, CIR is soliciting information about the ingredient to include in the initial materials provided to the expert panel; isn't that correct?
A. Technically I believe that is true, but I would disagree that that is something that happens routinely. But I would agree that -- I would say technically you may be -- that is something that could occur, yes, but that is not the situation, for example, in the case of talc.
Q. Why not?
A. Based upon what I have seen described as how the review was done, and that has to do with the testimony of different -- or different documents that I've reviewed and the testimony of individuals related to this document.
Q. Well, Dr. Cramer could have submitted comments to the CIR regarding talc, couldn't he?
MR. MEADOWS: Objection.
MS. PARFITT: Objection.
THE WITNESS: You'd have to ask

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Dr. Cramer if he was aware that they were reviewing it. I can't answer that for Dr. Cramer.
But if he was aware of it, certainly -- if you're aware of the process going on and the timing of it, certainly you can submit comments. I'm not disagreeing with you on that. That is true.
QUESTIONS BY MR. LOCKE:
Q. CIR publishes in advance what it's going to review; isn't that correct?
A. What is coming up for review?
Q. Yes.
A. Yes, things that are proposed for the next meeting, yes, that's true.
Q. And you could submit comments to the first draft of the CIR report; isn't that correct?
A. I would agree that that is possible to happen, yes.
Q. And you can submit comments before the final report is drafted, correct?
A. Yes, as long as it's still in draft form, yes, those comments can be

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submitted.
Q. And CIR meetings are open to the public, right?
A. That is true, they are open to the public, but in my experience it -- they are not meetings that are heavily attended by the public but indeed are -- tend to be meetings attended by industry stakeholders within the ingredients that are being reviewed.
Q. You know Mr. Steinberg here. He was a plaintiff's expert for a while?
A. I don't know him personally, but I know his name and I know he was a plaintiff's expert, yes.
Q. You know he attended the talc meeting, right?
A. Yes, I believe he was working with indus -- he works with industry, so I believe indeed he did attend that meeting.
Q. You're not claiming he was working with any industry member regarding talc, are you?
A. That's not what I stated. I know he's a consultant to the cosmetic

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industry, so it doesn't surprise me. And I believe he lives in the area, so it doesn't surprise me that he attended.
I haven't spoken to him about any of that, though, so I have no specific details of that.
Q. Transcripts of the meeting are available to the public, right?
A. You can download the transcripts, yes.
Q. They're on the website?
A. That's what I said. You can download. I'm sorry.
Q. Okay.
A. Yes, you can download them from the website.
Q. Did you submit comments to the CIR regarding talc?
A. No, I did not.
Q. Why not?
A. I wasn't aware of the process that was going on in the draft form at the time.
Q. Why is that?
A. I was not following the CIR for

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talc at that particular time. I have a lot of other clients and a lot of other issues that go on on a routine basis, and I -- I literally would not have time to follow every assessment they do, considering that they do thousands of chemicals.

Q. Did you know of the CIR prior to your retention by plaintiff's counsel?

A. Yes. In fact, I -- one of the journals that I receive, International Journal of Toxicology, maybe, publishes many of their safety assessments. So I certainly am, yes.

I was aware -- when I was at Eviron, I was aware of the existence of CIR.

Q. Have you ever provided prior to this litigation -- and by "this litigation" I mean any aspect of the talc litigation -- an expert opinion on cosmetics' ingredients?

A. You're asking me in any other litigation on a cosmetic ingredient?

I'm thinking back to the cases I've worked on. Not as a -- not as a testifying expert.

At Eviron, though, we worked on

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litigation involving cosmetic ingredients, thought I was not the testifying expert.

Q. In your report you talk about the percentage of -- or the number of ingredients that the CIR listed as unsafe.

Do you recall that?

A. Yes. I mean, if you want me to verify the number, I need to go there. But, yes.

Q. You don't mention that CIR has put limitations on approximately 50 percent of the ingredients that it has reviewed, do you?

A. I don't mention that, but they do. They have -- they have -- when they have a statement about safety, they will -- they will often talk about the limitations from the safe use based on either concentration or even maybe route of exposure, that is true.

Q. Why don't you do that? Why didn't you include that in your report?

A. No particular reason. I mean, the point I'm trying to make is really the workload that's going on here and the impossibility of the task of providing the

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same level of review of any of these ingredients as can be provided -- as was provided by the IARC.

And so, again, that's one of the comparisons I'm doing. I'm talking about the difference in the time, the effort, the difference in the independence of the reviews. And so that -- when I'm talking about, those numbers, that's what I'm focusing on. I'm focusing on the fact that you have so many reviews in a very short period of time, with a one-expert panel, it's impossible for that level of analysis and review to be anywhere near what IARC panels do, and also nowhere near the level of review that I have done based on the number of documents that I have analyzed and looked at. So it's a different type of review.

Q. Let me ask you a few questions because you have criticized the panel.

You would agree with that, correct?

A. Yes. Oh, absolutely. This particular analysis I have. I have made some general criticisms of the overall process,

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and then I made some specific criticisms of this particular review.

Q. And one of your criticisms is that the CIR -- I think you said two CIR expert panelists had conflicts of interest; is that correct?

A. Yes, that -- they did, that were not -- that were not -- I believe not understood even by Dr. Andersen at that time. I think these are things brought up to him that he was not aware of.

Q. All right. Now, you read his testimony in one of the trials in California, right?

A. Yes, that's the -- in fact, that's the source of the information where I'm citing to those names of those individuals. I think I refer to that, his trial testimony.

Q. And didn't he, though, say, well, he didn't view it as a conflict of interest because the money wasn't going to them personally, it was going to their organizations?

A. He did make that statement,

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yes.
Q. And you disagree with that statement?
A. I don't -- I mean, his testimony is what it is.
Are you asking me do I disagree that that's a conflict of interest?
I disagree that you shouldn't disclose that as a potential conflict in the documents that are produced, just like I do when I write an article and I disclose that I've had funding. I don't say what the funding specifically paid for, but I've had funding or support from this industry individual or that industry individual. It's -- it's something that just is about transparency.
Q. So when you write articles, you say that you've been paid a lot of money by plaintiffs' lawyers?
MR. MEADOWS: Objection.
MS. PARFITT: Objection.
THE WITNESS: Well, I haven't written an article that overlaps with an issue that I've addressed in

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plaintiffs' litigation, but I certainly have given my conflict of interest statements that relate to the issue in the article.
I do that -- I've done that with -- on my work -- several of my -- several of my assessments talking about risks of pesticides. I've done it with the work that I've done that that's been sort of, I guess, policy-type work on behalf of the American Chemistry Council.
So absolutely I do.
QUESTIONS BY MR. LOCKE:
Q. Okay. You don't think it's relevant that you receive 50 percent of your money solely from plaintiffs' products liability lawyers?
MR. MEADOWS: Objection.
MS. PARFITT: Objection. Form.
THE WITNESS: If it has nothing to do with the issue that I'm addressing in the paper, no, I do not think that.
But when you're accepting money

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from an industry or a company that has to do with the issue you're looking at, yes, a conflict -- a conflict of interest absolutely needs to be described.
QUESTIONS BY MR. LOCKE:
Q. And that would -- well, let me just ask you: You're not an ethicist, are you?
A. No, I'm not trained as an ethicist.
Q. And you're not a lawyer, are you?
A. Well, no, but I have passed the patent bar, but I'm not trained as a lawyer.
Q. That doesn't make you an ethicist, right?
A. No, it does not.
Q. Okay. Let's talk about one of the people you criticized, Dr. Wilma Bergfeld.
Did you know she was the first woman who was the president -- to be the president of the American Academy of Dermatology?

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A. No, I don't know her personally, so, no, I did not know that.
Q. Did you investigate her at all when you criticized her?
A. I wasn't criticizing her, I was criticizing the CIR process for failing to disclose the conflicts of interest of individuals that were involved in their assessment.
I certainly am not giving personal criticism to either of those individuals.
Q. You would agree that the American Academy of Dermatology is a reputable organization?
A. I haven't formed an opinion one way or the other; however, I'm aware of them, and certainly I know individuals that are members of it, yes.
Q. Are those individuals reputable people?
MS. PARFITT: Objection.
THE WITNESS: They are people that practice medicine that certainly I would go see. I mean, you're asking

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me if I formed a very specific opinion about them as individuals, and I haven't done that.
QUESTIONS BY MR. LOCKE:
Q. Do you have any reason to believe that the American Academy of Dermatology is disreputable?
A. No. Again, I haven't formed an opinion one way or the other. I'm aware of the organization, and it certainly is one that is -- has within its members a number of people that I know that practice in dermatology.
Q. Did you know that Dr. Bergfeld was the first woman to be president of the Cleveland Academy of Medicine?
A. To the what? What was the first word?
Q. Cleveland Academy of Medicine?
A. No. Again, I'm not aware of her CV specifically, other than what may have been discussed -- it's possible her -- I know her affiliation will be listed in some of the documents as to where she is today, but I do not know her CV and her history.

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Q. Are you aware that she was the first president -- or she was a president of the American Society of Dermatopathology?
A. No. Same thing. If I'm not aware of her CV, I wouldn't know that.
Q. How about that she was the former chair to the FDA's drug -- FDA's Dermatology and Ophthalmology Advisory Committee?
A. Same answer. I don't know her CV, so I have no knowledge.
Q. Is it your opinion that Dr. Bergfeld was not qualified to chair the CIR panel that considered talc?
A. I don't think I formed that specific opinion. Instead, what I have -- the opinions I formed relate to the overall makeup of the panel that failed to include individuals with expertise that were -- that are really key to assessing the safety of talc. And that had to do with the issues of, as I discuss it, epidemiology -- oh, I'm sorry, I think I need to put this back -- period -- sorry. In the area of epidemiology is one that I talked about it specifically,

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and also gynecological -- gynecological sciences on the issue of migration.
Q. You're not a epidemiologist, are you?
A. Not by training. It's a tool I use all the time, but I'm not an epidemiologist by training.
Q. And panel members on the CIR, they might have used the same tool that you're using to form your opinion about talc, correct?
MR. MEADOWS: Objection.
THE WITNESS: Based on what I've reviewed from the minutes and the write-up, I would disagree that that is -- they have done -- they've used the tools in the same way I have. I disagree with that.
QUESTIONS BY MR. LOCKE:
Q. No, but I'm saying their epidemiology could be the same background that you have. You haven't reviewed who they are, so you really don't really know.
MR. MEADOWS: Objection.
THE WITNESS: Well, I do

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know -- I do know Dr. Klaassen, who I believe was on the panel as a toxicologist. He is not somebody that -- he is not somebody that I understand does a significant amount of evaluation in risk assessment for epidemiological studies. He has done some of that, yes, I agree, but it's different training than mine.
QUESTIONS BY MR. LOCKE:
Q. You're better qualified than he is?
A. No, that's not what I'm saying. I'm saying it's different background.
The question that I heard you ask me, I believe, was directed towards the differences in my background versus somebody else's.
And I'm saying that I'm not aware that he has the same background I do, but there is not -- there was not somebody on the panel that had specific expertise and analysis of epidemiological studies as an epidemiologist. And I think that's important in this case where you're analyzing in a

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causation analysis a wide variety of studies. So I do think it's important.
Q. You're not a gynecological oncologist, are you?
A. No, I'm not. But again, that would have been an important expertise to have on the panel when --
Q. And yet you formed your opinion with --
MR. MEADOWS: Hold on.
MR. LOCKE: No. No. Go ahead. You can ask follow-up questions if you want.
MR. MEADOWS: You're interrupting her.
MR. LOCKE: Well, I've got a limited amount of time, and I've got to keep moving.
MR. MEADOWS: Well --
MR. LOCKE: They're very long answers to questions that I'm not asking. So I -- you follow up if you would like with your questions, but I got to keep moving.
MR. MEADOWS: Well, I'm sorry,

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but you're not going to be allowed to interrupt her.
MR. LOCKE: Okay. Then we'll go longer. If she's going to answer questions I'm not asking, then I need to go -- I need to be able to go longer.
MR. MEADOWS: You're not going to be allowed to interrupt her.
That's just the bottom line.
QUESTIONS BY MR. LOCKE:
Q. You're not a gynecological oncologist, right?
A. I'm not trained as a gynecologic oncologist, that is true.
Q. You're not a medical doctor, correct?
A. I am not a physician, that is correct.
Q. Let's talk about the citizens petition.
The FDA frequently seeks scientific information from cosmetic manufacturers; is that correct?
A. First part of the question?

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I'm sorry.
Q. The FDA frequently seeks information, scientific information, from cosmetic manufacturers; is that correct?
A. I don't understand what you mean by "frequently seeks." They rely on cosmetic manufacturers to do their own safety assessments.
Is that what you're referring to?
Q. Well, they ask PCPC to comment on scientific issues, correct?
A. Yes, I would agree that that interaction has happened, but that's not where the responsibility lies. But I agree, they have.
Q. I'm not asking about responsibility. I'm asking: Has the FDA asked cosmetic manufacturers for scientific information?
A. Yes, they have in this case. I discuss some of that, yes.
Q. And they do that frequently, right? Not just in this case, but generally?
A. I can't answer that for all

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situations. I have seen it happen before, yes.
Q. The FDA asked, for example, for then CTFA to cosponsor the 1994 workshop on talc, correct?
A. Yes, they did.
Q. The FDA knew that the report prepared by Dr. Huncharek and Dr. Muscat was based on PCPC's retention of those consultants, correct?
A. So what are you -- what time period are you talking about?
Q. Well, now, there was only one time that Drs. Huncharek and Muscat submitted a report to the FDA regarding talc, correct?
A. So I need to look to confirm that. Which time period are you talking about?
Q. 2009. Citizens petition.
A. Oh, that is true. In the citizens petition, that is true, yes. But I -- but...
Q. I mean, it says in the letter, "We're submitting a report written by Drs. Huncharek and Muscat," correct?

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A. In the cover letter from the CRE?
Q. From -- not CRE, from PCPC.
A. Okay. So let -- I need to -- I need to refresh my memory on the way the submissions were made. I apologize.
Do you remember which paragraph that you're referring to?
Q. Well, it's throughout your report you're talking about the citizens petition.
A. So it's my recollection, based upon the documents that I have seen, that it was not a transparent process at all times that Drs. Huncharek and Muscat were being identified as independent consultants and were not ones that were being actually paid by the industry for some of the work that they did. And I think that's discussed in my report.
Q. Well, let's break that down.
A. If you want me to confirm the issue of the 2009 -- if you will point me to where you say I discuss this, I will confirm that or not.

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Q. Well, let me break it down.
Citizens petition submitted in 2008, right?
A. Well, there were two: one in 1994 and another -- I'm sorry, 1992, and another in 2008.
Q. Well, there are actually several more than that, but let's just focus on the 2008.
In 2008, a citizens petition was submitted?
A. Yes, that is true.
Q. And PCPC responded to that citizens petition in 2009, correct?
A. They submitted comments. Is that what you're asking me? Yes, they did.
Q. Yes.
And that was a cover letter, correct?
A. A cover letter -- that's all it was was a cover letter?
Q. Well, attached to the cover letter was a report from Drs. Huncharek and Muscat?
A. Yes, that is true.

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Q. And you're not aware of any other document indicating that PCPC ever hired Drs. Huncharek or Muscat?
A. So that's where I'll need to go back and look at the documents, because -- that I have discussed. So I need to find that on my paragraph.
If you want to go off the record for a minute so I don't waste your time, I will look.
Q. Sure.
A. It's up to you. Or we can stay on the record.
MR. LOCKE: I'm fine going off.
VIDEOGRAPHER: We are going off the record at 4:23 p.m.
(Off the record at 4:23 p.m.)
VIDEOGRAPHER: We are back on the record at 4:25 p.m.
QUESTIONS BY MR. LOCKE:
Q. The question I asked: Are you aware of any other document indicating that PCPC ever hired Dr. Huncharek and Muscat other than for the 2009 response or submission to the citizens petition?

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A. I would have to pull this document, but in paragraph 90 I make a statement: A 2005 response written by Dr. Muscat says -- this is not '09, this is 2005, and Dr. Huncharek critiqued the work of Dr. Cramer, who also failed to disclose the financial relation -- I'll start over.
Okay. So I'm sorry to repeat myself, but there was a little noise.
You asked 2009. So the other time period I have in my report in paragraph 90 talks about 2005, but I'd have to pull this document.
But I am citing to the deposition of Dr. Loretz, who was a PCPC employee, so I think I would need to pull this in order to confirm.
But I see depositions of her and Dr. Nicholson as talking about them failing to disclose the financial relationship between their work and industry.
Q. So if Dr. Loretz did not testify that PCPC had retained Drs. Huncharek and Muscat in 2005, you'd have no other evidence?

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A. I can't answer that definitively, but this is what I would point you to. So I'd have to pull these documents to confirm, but I have -- both paragraphs 89 and 90 address these general issues for you, but I think that's the sentence and the documents that I think would be relevant. But I'd have to pull them to fully answer your question.

Q. The reason I ask the question is because you frequently say "the cosmetics industry" without identifying a party or a person. And -- well, I'll just leave it at that.

A. And I guess the reason I'm saying I need to -- I'm questioning that it doesn't have to do with PCPC is because I am citing to a deposition of their employee. So I need to -- I would -- to affirm it, though, I'd need to -- I don't want to say that 100 percent the answer to your question is this is the evidence, but I believe that I would need to go here to confirm one way or the other. But certainly I would -- this raises suspicion about that for me.

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Q. You have no evidence that PCPC ever retained the Center for Regulatory Effectiveness; is that correct?

A. I believe my evidence is hiring through Imerys, but let me look to make sure that is true.

Q. Why don't you look at page -- or I'm sorry, paragraph 95, page 63.

A. That's where I am. That's where I am, so let me read what I have here because it's been a while since I've read this paragraph.

So the question is, do I have in evidence this paragraph that PCPC directly hired the CRE?

No, that is not provided by this paragraph.

Q. Okay.

A. However, in this paragraph, based on these documents that I'm seeing and I'm -- my memory of what is discussed, certainly I believe PCPC would have been aware of the interaction of CRE at these time points when I'm talking about this event -- these events.

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Q. What evidence do you have of that?

A. Based upon the close interaction between PCPC, Imerys and Johnson & Johnson throughout these time periods when different actions were being taken to comment or to submit information on behalf of industry.

Q. Do you have a single document you can point to or is that an assumption?

A. That is something I seem to remember based on my review of these documents, but if you need a document, I would have to -- have to go and look for it.

Q. Sitting here today, you can't recall?

A. I can't give you a specific document as I sit here today, no.

MR. LOCKE: I have no further questions.

MR. MEADOWS: Yeah, short break. Maybe we're done, maybe we're not.

VIDEOGRAPHER: We are going off the record at 4:30 p.m.

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(Off the record at 4:30 p.m.)

VIDEOGRAPHER: We are back on the record at 4:45 p.m.

CROSS-EXAMINATION

QUESTIONS BY MS. PARFITT:

Q. All right. Dr. Plunkett, good afternoon. I know it's been a long day.

Dr. Plunkett, you were asked throughout the course of the day about different constituents which are part of the talcum powder products.

Do you recall those questions?

A. Yes.

Q. All right. If -- without going through each and every one of different constituents that we've talked about that are contained or could be contained in the talcum powder products, if they are present, do those various constituents present and provide biologically plausible evidence that talcum powder products can increase the risk of ovarian cancer?

MS. BOCKUS: Object to the form.

THE WITNESS: Yes, which is --

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I think I have a couple of paragraphs where I talk about that issue. It has to do -- there's other information as well, but that is a key piece of that information. And I focused on mode of action and additivity. That's on mechanism, biologic plausibility.

So the fact that you have a variety of constituents that have a known cancer hazard that share a mode of action, that increases your confidence in the biologic plausibility of that relationship between ovarian cancer and exposure to talc body powders, yes.

MS. PARFITT: Thank you. I have no further questions. Thank you very much, Dr. Plunkett. And a happy holiday to you.

THE WITNESS: Thank you.

MS. BRANSCOME: I have no questions.

MS. BOCKUS: No questions.

VIDEOGRAPHER: The time now is 4:47 p.m. This concludes the

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deposition, and we are going off the record.

(Deposition concluded at 4:47 p.m.)

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CERTIFICATE

I, CARRIE A. CAMPBELL, Registered Diplomate Reporter, Certified Realtime Reporter and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, Laura Plunkett, Ph.D., DABT was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

_____

CARRIE A. CAMPBELL,
NCRA Registered Diplomate Reporter
Certified Realtime Reporter
California Certified Shorthand Reporter #13921
Missouri Certified Court Reporter #859
Illinois Certified Shorthand Reporter #084-004229
Texas Certified Shorthand Reporter #9328
Kansas Certified Court Reporter #1715
Notary Public

Dated: 12/20/18

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ACKNOWLEDGMENT OF DEPONENT

I,_____________________, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
Laura Plunkett, Ph.D., DABT DATE

Subscribed and sworn to before me this
_______ day of ______________, 20 _____.
My commission expires: ______________

Notary Public

ERRATA

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